



# Why FDA Has Adopted HACCP Regulations to Ensure the Safety of Food

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## **Why FDA Has Adopted HACCP Regulations to Ensure the Safety of Food**

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## Abstract

HACCP (Hazard Analysis and Critical Control Point) is a form of statistical quality control adopted by FDA as a regulatory tool to ensure the safety of seafood and juice products. HACCP evolved from the teachings of Walter A. Shewhart and W. Edwards Deming, pioneers in the field of statistical quality control. Their revolutionary concept—controlling the quality of the product by controlling critical steps in the product’s manufacture rather than relying upon end-product inspection—provided manufacturers with a scientific means of identifying and preventing potential hazards from impairing product quality. FDA adopted HACCP-like regulations for low-acid canned foods and acidified foods in the 1970s, requiring food processors to control the heat sterilization portions of their manufacturing processes in order to prevent botulism toxin from forming in the final product. The regulations identified the hazards and manufacturing controls to be instituted—tasks that HACCP leaves to the manufacturer. Indeed, FDA adopted seafood HACCP regulations in 1995 as a means of shifting the burden of identifying the myriad seafood hazards and appropriate manufacturing controls from the Agency to food processors. Although both FDA and industry have struggled in their transition to a HACCP system, federal regulators continue to view HACCP with favor. In 2001, FDA chose HACCP for its regulation of juice products, finding HACCP to be a flexible regulatory tool that both promotes industry self-education and allows manufacturers to engage in innovative methods of quality control. Although pure HACCP regulations continue to be unpopular with some members of the food industry, the concepts underlying HACCP are likely to inform FDA’s promulgation of current good manufacturing practices for the food and dietary supplement industries.

## Introduction

HACCP (Hazard Analysis and Critical Control Point) is a scientific quality control method used in various industries to ensure that manufactured goods meet certain quality and identity standards set by the manufacturer. The U.S. Food and Drug Administration (“FDA”; “the Agency”) and U.S. Department of Agriculture (“USDA”) now require certain food manufacturers to institute HACCP plans in order to ensure the safety and quality of high-risk foods within the food supply. A HACCP compliance program consists of seven principles:

- (1) Conduct a hazard analysis;
- (2) Determine the critical control points (CCPs);
- (3) Establish critical limits;
- (4) Establish monitoring procedures;
- (5) Establish corrective actions;
- (6) Establish verification procedures; and
- (7) Establish record-keeping and documentation procedures.<sup>1</sup>

The seven principles of HACCP outline a procedure whereby food manufacturers can identify potential safety and quality hazards associated with their food product; identify portions or steps of the manufacturing process—critical control points (CCPs)—at which precautions can be taken to avoid the appearance of

such hazards in the final food product; establish procedures whereby those critical portions of the manufacturing process can be monitored, verified, and, if necessary, corrected; and establish a record-keeping system that provides manufacturers with documentation of the proper functioning of their manufacturing process, documentation that also enables the manufacturer to demonstrate compliance with good manufacturing practices requirements under federal law.

FDA currently requires seafood and juice manufacturers to institute HACCP plans, and has adopted HACCP principles in its regulation of low-acid canned foods and acidified foods. FDA also has implemented voluntary HACCP programs for dairy “Grade A” products (in conjunction with the National Conference on Interstate Milk Shipments), food service establishments (restaurants) and food retailers (supermarkets).<sup>2</sup> USDA requires manufacturers of meat and poultry products to comply with HACCP plans.<sup>3</sup>

Although the adoption of HACCP as a regulatory compliance tool is a relatively recent phenomenon, the quality control concepts embodied within HACCP date back at least over 70 years and themselves reflect the advances in manufacturing and quality control made during the Industrial Revolution.<sup>4</sup> This paper reviews the development of and rationale behind statistical quality control methodologies in manufacturing (parts I to III); the application of HACCP-like quality control measures to the manufacture of low-acid canned foods (part IV); and the advantages and disadvantages of HACCP, as viewed through the lens of FDA’s regulation of seafood (parts V to VIII) and juice (part IX). The paper concludes with a brief outlook at the future of HACCP (part X). Throughout the discussion, this paper introduces the reader to the HACCP concepts and regulations, and explains why HACCP continues to gain in importance in the areas of food quality and safety.

## Part I

The term quality control refers to any set of activities designed to ensure the quality of a product.<sup>5</sup> Although commonly used in the context of manufactured goods, the term quality control also applies to the production of food products including agricultural goods. Indeed, selective breeding of animals and plants in agriculture can be characterized as efforts to control the final quality of agricultural goods. Through artificial selection, a farmer may seek to increase milk production in cows, increase the average egg production of his chicken population, or grow and reproduce wheat with rust resistance.<sup>6</sup> Furthermore, the use of specialized cultivation methods, machinery, fertilizers, insecticides, and herbicides also represent longstanding and widespread agricultural quality control measures. Let us not forget visual, tactile and olfactory inspection of the final agricultural products by the producer, perhaps the simplest and most direct means of checking the quality of the food product. Finally, to the extent our consumer complaints reach the farmer’s ears, each one of us directly engages in quality control, using our criticisms and complaints of the final agricultural product to help the farmer create a better and better-accepted consumer product.

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<sup>2</sup> See generally FDA’s website for HACCP. Online at <http://www.cfsan.fda.gov/~lrd/haccp.html>.

<sup>3</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule, 61 Fed. Reg. 38806 (July 25, 1996).

<sup>4</sup> See generally Walter A. Shewhart, *Statistical Method from the Viewpoint of Quality Control* (W. Edwards Deming ed., 1939).

<sup>5</sup> See, e.g., Webster’s Ninth New Collegiate Dictionary 963 (1991).

<sup>6</sup> Anthony J.F. Griffiths et al., *An Introduction to Genetic Analysis* 805-807 (6th ed., 1996).

Quality control of food products, therefore, dates back thousands of years. It is not a new or specialized endeavor. Yet, because of technological and sociological changes, modern food production in the industrialized world hardly resembles that of a century ago. Scientific advances and new food technology have dramatically expanded the food choices available to consumers. Furthermore, the 20th century witnessed drastic changes in demographics, lifestyle choices, disposable income, and price of consumer goods, resulting in a marked shift away from self-harvesting, self-storing, and self-processing of foods.<sup>7</sup> In particular, the size of households decreased, and the number of elderly increased; women increasingly joined the work force and sacrificed leisure time which might have been spent preparing meals; real per capita disposable income rose, allowing households to expend more resources on food; and the price of prepared foods became cheaper than their home-prepared counterparts (factoring in the costs of time and labor). Families, with increased income and decreased leisure time, increasingly turned to prepared foods and food-away-from-home, which largely consisted of processed and pre-prepared foods.<sup>8</sup>

Consumers shifted their preferences away from traditional, locally-produced agricultural goods, many of which needed only simple quality control plans, towards mass-produced agricultural and processed foods, which often required special means to ensure the foods' sterility and quality as they journeyed their considerable distance from manufacturer to consumer. This shift dramatically impacted the manner in which the federal government would need to regulate food and quality control. As Archibald and Dahl noted:

[T]rends in consumer tastes and preferences raise some new regulatory issues. The trend toward consumption of fully and partially prepared foods, eaten either at home or away from home, increases the potential for food-borne disease related to its handling and also introduces additional 'critical control points' into manufacturing processes. Likewise, while consumer interest in diet and nutrition provides firms with the opportunity for new product development, it is also likely to raise new regulatory issues related to product content, identity, labeling and advertising.<sup>9</sup>

With the introduction of new advances in food technology, manufacturing, and transportation also came the introduction of new accidents that arose when the technology failed. Of particular concern to manufacturers, regulators, and public health officials was the potential for widespread microbiological contamination of new food products. Accordingly, the National Academy of Sciences' Ad Hoc Subcommittee on Food Microbiology published a report in 1964 calling upon industry and government to collaborate on the following quality control activities: (1) improvement in the detection, investigation and reporting of foodborne disease; (2) continuous monitoring of potentially hazardous foods for microbial contamination; (3) development of improved technologies for identifying microbial agents of foodborne disease; (4) modernization of food protection programs and practices; and (5) increased research and education in food microbiology and other fields concerning food and public health.<sup>10</sup>

The following years saw repeated calls for attention to the problem of foodborne disease and quality control.

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<sup>7</sup> Jean Kinsey and Dale Heien, *Factors Influencing the Consumption and Production of Processed Foods*, in *Economics of Food Processing in the United States* 47-48 (Chester O. McCorkle, Jr. ed., 1988).

<sup>8</sup> *Id.* at 47-61.

<sup>10</sup> See Symposium, 1971 National Conference on Food Protection 21 (1971) (Statement of Keith H. Lewis, Ph.D., Director, Office of Food Sanitation, Bureau of Foods, FDA). The 1971 National Conference on Food Protection was sponsored by the American Public Health Association and published by the U.S. Dept. of Health, Education, and Welfare; Food and Drug Administration; Public Health Service.

In 1971, the American Public Health Association (APHA), with funding from FDA, organized a National Conference on Food Protection attended by members or representatives of APHA, FDA, USDA, the Canadian Food and Drug Directorate, the Food and Agriculture Organization of the United Nations, and the food industry.<sup>11</sup> Various speakers recognized that modern changes in food consumption habits and food technology had created the potential for widespread foodborne illness. One conference workshop noted, Beginning at least five years ago, the major food poisoning outbreaks have originated in schools, canteens, hospitals, restaurants, cafes, delicatessens, socials, catering organizations, and other mass feeding places. This is not due solely to mounting hazards, but also to an enormous increase in the number of meals and meal components prepared away from home.<sup>12</sup> William O. Beers, bacteriologist and president of Kraftco Corp, lamented that advances in food safety had not kept up with advances in food production; he stated, Where we have had a literal revolution in food production, processing, and service and retailing facilities, with a resulting multiplication of the possibilities of microbial contamination, food safety measures have essentially failed to keep pace with overall advances.<sup>13</sup>

The 1971 APHA conference workshop reports urged a revolution in food safety regulation in order to ensure that the revolution in food technology not be overshadowed by the technology's potential hazards. Importantly, the workshop participants recognized that an effective food safety regulatory program would necessarily require oversight of food producers' quality control programs. For example, the workshop on the Prevention of Contamination of Commercially Processed Foods concluded that the implementation of *general* good manufacturing practices (GMPs) requirements alone would not suffice to prevent against microbial contamination; the report suggested that because the potential for microbial contamination of different food products necessarily depended upon the characteristics of the food product and its manufacturing processes, effective microbial control would require effective control and oversight over the critical control points (CCPs) in the manufacturing process and subsequent handling of the finished food product.<sup>14</sup> CCPs are critical points in the entire food production process, from obtaining the raw materials to consumption of the finished product, at which the hazards of microbial contamination, poor quality, or other unwanted characteristics can be addressed and prevented by the implementation of certain controls. The workshop identified potential CCPs with regard to the handling of raw materials, processing the raw materials (including the design of equipment and cleaning procedures), environment, personnel (e.g., workers' handling of food), finished products (recommending an audit system for testing products from manufacturing lines and from the field), and distribution (e.g., refrigeration of the finished product during distribution).<sup>15</sup>

FDA proved to be very receptive to the workshop's recommendations. The Vice Chairman of the workshop on the Prevention of Contamination of Commercially Processed Foods was Howard E. Bauman, Ph.D., of the Pillsbury Co. Under contract to provide food for NASA's space program, Pillsbury had implemented a quality control program that focused upon the identification, monitoring, and control of CCPs.<sup>16</sup> Dr. Bauman believed that such an approach to quality control was necessary if the food industry was to meet its

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<sup>11</sup> *Id.* at II-III (Preface).

<sup>12</sup> *Id.* at 143 (Report from Workshop 7: Training and Utilization of Professional and Nonprofessional Manpower).

<sup>13</sup> *Id.* at 27-29 (Statement of William O. Beers, President, Kraftco Corp.).

<sup>14</sup> *Id.* at 56-83 (Report from Workshop 2: Prevention of Contamination of Commercially Processed Foods).

<sup>15</sup> *Id.*

<sup>16</sup> Bud Hazelkorn, *The HACCP Epic*, Meat Processing, North American Edition (2004). Online at [http://www.meatnews.com/mp/northamerican/dsp\\_particle.mp.cfm?artNum=551](http://www.meatnews.com/mp/northamerican/dsp_particle.mp.cfm?artNum=551).

obligation of improving its manufacturing processes and producing safe food.<sup>17</sup> FDA shared Dr. Bauman's beliefs, and Pillsbury entered a contract with the FDA to train the Agency in its quality control methods. The Pillsbury training course had a demonstrable effect on FDA's regulatory approach to ensuring food safety. In a 1972 Symposium on Newer Food Processing Technology, attended by representatives from industry, FDA, USDA, state and Canadian health departments,<sup>18</sup> FDA official Dr. Virgil O. Wodicka explained the Agency's new regulatory priorities:

The program of the Food and Drug Administration in enforcing the law over the last generation has put primary emphasis on operating conditions in the processing plant on the day the inspector came in. This would detect practices that were habitually wrong or that happened to be wrong on that day. If they were bad 10 percent of the time and the inspector came in on the average of once every 6 years, the chance of detection, much less correction, was not very great. It is now the intent of the Food and Drug Administration to convert as rapidly as it can to a system of inspecting the producer's quality control. If the producer can demonstrate good quality control he will qualify for a minimum of attention. If his quality control is found defective or if he is sufficiently defensive to refuse to disclose it, he will earn increased attention in proportion to the assessment of the likelihood of the hazard.<sup>19</sup>

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[Offering broad guidelines as to FDA's new approach in evaluating quality control programs, Wodicka stated:] Let me use some of the jargon we are now taking advantage of in the training course that we have contracted with Pillsbury to develop for us, that is, to identify the 'critical control points.' These are the points that will make or break the process, such as places where contamination can be introduced, or where contamination is reduced. At these critical points, the question is what controls are necessary and to what extent are they necessary. The audit of a system would consist of the identification of these points, and the assessment of the adequacy of control that is in effect at those points. Obviously, there has to be some kind of feedback control, so it is not just a matter of writing a history. It is a matter of modifying the operation to correct any variations from the state of control that are found.<sup>20</sup>

Dr. Wodicka's statements revealed a recognition that food inspections no longer sufficed to prevent microbiological contamination of food or ensure the safety and quality of the food supply. Over the 20th century, food inspection agencies relied heavily upon food inspection to police the safety of the food supply. However, in the age of mass production, new food technology and globalization, a regulatory system focused upon inspection was neither feasible nor desirable to regulators or manufacturers.

As Dr. Wodicka noted, inspection of finished food products may not establish a reliable account of the safety of food entering the food supply. With limited resources and a limited number of inspections, the FDA could

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<sup>17</sup> Symposium, Proceedings of a Symposium on Newer Food Processing Technology. August 14-16, 1972. Safety and Quality Assurance. Pages 2, 108 (American Medical Association 1973). The 1972 Symposium on Newer Food Processing Technology was sponsored by the American Medical Association (AMA) Food Industry Liason Committee and the Food Science Committee, Council on Foods and Nutrition.

<sup>18</sup> *Id.* at 267-69.



not ensure that periodic, intermittent inspections could detect chronic, intermittent hazards.<sup>21</sup> Inspectors might show up on the one day when the manufacturer's problems did not materialize. Furthermore, inspection of finished food-products is expensive and time-consuming to both manufacturers and regulators. Inspection often requires testing and destruction of large amounts of the finished product in order to gain a statistically powerful and accurate conclusion as to safety. With regards to microbiological tests, rapid, reliable and efficient tests were scarce; accurate tests often were too cumbersome and time-consuming to constitute a regular part of the manufacturing process, and quick homebrew tests developed by manufacturers often lacked validation and recognition by regulatory officials.<sup>22</sup> Microbiological tests were also limited in their usefulness in day-to-day inspections, because results from such tests often were not immediately available.<sup>23</sup>

The lack of a single, uniform system of food regulation also decreased the effectiveness and efficiency of food inspection programs. The president of the APHA asked, [W]hy do persons from 10 to 30 local agencies, 4 or 5 states, and 2 or 3 Federal agencies have to inspect the same establishment?<sup>24</sup> The multitude of inspection programs—each having different perspectives, responsibilities, objectives, standards, and enforcement policies—complicated manufacturers' compliance efforts and sometimes placed great responsibility in the hands of ineffective state or local programs. This regulatory system, fractionated into various parts and governed by the different concerns of the local, state, and federal governments, appeared to be obsolete and unworkable, especially given the increasingly national and international nature of food production and distribution.<sup>25</sup>

Given this background, industry and regulators increasingly saw industry self-inspection as a solution to enhancing the quality and safety of food, while simultaneously reducing the burden on regulatory agencies. The proposed industry self-inspection would not simply replace the ineffective and costly end-inspection by regulators with similar end-inspection by manufacturers. No, this proposed self-inspection would shift its focus to the entire manufacturing process in order to detect sources of contamination or poor quality. It would draw upon the lessons learned from the management and quality control revolution in other industries, as pioneered by Walter A. Shewhart, W. Edwards Deming, and others. These lessons follow.

## Part II

As discussed above, the concept of quality control has been with us for the ages. However, events during the 20th Century helped to spur a revolution in quality control, perhaps none so influential as the two World Wars, and the resulting need for high quality, mass produced goods.<sup>26</sup> The late 19th century had seen Frederick Taylor's introduction of scientific management of the production line, and the early 20th century had seen Henry Ford's introduction of the moving assembly line. But these innovations focused

<sup>21</sup> In FY 1971-72, FDA employed 242 food inspectors. Peter Barton Hutt and Richard A. Merrill, Food and Drug Law 232 (2d ed. 1991).

<sup>22</sup> 1971 National Conference on Food Protection, *supra* note 10, at 63 (Report from Workshop 2: Prevention of Contamination of Commercially Processed Foods).

<sup>23</sup> 1971 National Conference on Food Protection, *supra* note 10, at 13 (Statement of P. Walton Purdom, Ph.D., President of APHA).

<sup>24</sup> *Id.* at 12.

<sup>25</sup> *Id.* at 11-13.

<sup>26</sup> George Mouradian, The Quality Revolution. A History of the Quality Movement 101 (2002).

upon facilitating and increasing production (e.g., through the use of standardized parts and coordination of various steps in the manufacturing process); they did not focus upon quality control per se, and up through the 1930's end-inspection of the final product remained manufacturers' primary quality control technique.<sup>27</sup> Thus, those innovations spoke more to the quantity of goods produced by mass production, rather than to their quality.

The revolution in quality control came from the application of statistical methods to the mass production of goods in the early 20<sup>th</sup> century. Walter A. Shewhart, the Father of Modern Quality Assurance," is given credit for pioneering this field.<sup>28</sup> In his lectures to the USDA Graduate School, Shewhart explained the rationale and historical development of statistical quality control. A brief summary of his teachings follows:

In the 19<sup>th</sup> century, the ideology of mass production characterized manufacturing as an exact science—i.e., as an attempt to reproduce machines and parts to exact dimensions.<sup>29</sup> However, manufacturers soon realized that it was very costly to make exact replicas. Furthermore, in most cases the costs were unnecessary; manufacturers could make replica parts that were not exact duplicates, but were close enough to the ideal so as to ensure a product of high quality. Thus, manufacturers adopted a go limit, a minimum clearance or threshold value at which the replica was close enough to being exact such that production could continue.<sup>30</sup>

The adoption of go limits proved efficient, but presented other difficulties in the context of the production of interchangeable parts. To illustrate the problem, imagine two interconnecting parts, Part 1 and Part 2. Part 1 may meet its go limit, and Part 2 may meet its go limit, but the two parts still may not properly fit together. The problem remains that the production of each part has not accounted for the subsequent use of that part with other connecting parts. In other words, the production of Part 1 must account for the subsequent interaction of Part 1 with Part 2. This is accomplished by the introduction of a "no-go" limit to complement the go limit. Around 1870, manufacturers began using go and no-go limits—lower and upper tolerance limits that ensured the proper interaction between two fitting parts.<sup>31</sup> As long as manufacturers produced parts that individually stayed within their go and no-go limits, the parts would fit together and manufacturers need not waste time and money being unnecessarily exact.

The quality control method described above focused entirely upon the physical characteristics of the end product. As such, it required inspection of the end product to determine whether the end product was defective—i.e., whether it exceeded the go/no-go limits. Under this approach, manufacturers bore the costs of inspection, as well as the costs of defective products. Thus, manufacturers sought to increase production efficiency by identifying the causes of defective products. More specifically, they aimed to reduce the percentage of defective products to the extent that it was economical—i.e., to the point where the cost of controlling the production process equaled the savings brought about by the decrease in the number of defective products.<sup>32</sup> Furthermore, manufacturers sought to institute a method of statistical sampling of end products that minimized the costs of inspections but also ensured quality.

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<sup>27</sup> *Id.* at 101-03.

<sup>28</sup> *Id.* at 87.

<sup>29</sup> Walter A. Shewhart, Statistical Method from the Viewpoint of Quality Control 2-3 (W. Edwards Deming ed., 1939).

<sup>30</sup> *Id.* at 3.

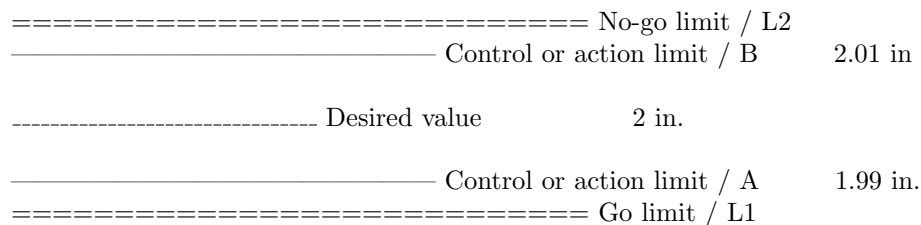
<sup>31</sup> *Id.*

<sup>32</sup> *Id.* at 4.

At the dawn of the 20<sup>th</sup> century, the challenge remained to create an efficient system of quality control that permitted the production of items within certain specifications and required a minimum of end-product inspection. Manufacturers tackled this challenge by linking the production process to the variability of the final product through statistical quality control. As described in further detail below, statistical quality control utilizes trends in statistical sampling of the finished product to indicate whether the manufacturing process is controlled or uncontrolled. When the results indicate an uncontrolled manufacturing process, a strategy is identified to correct the problem through changes to the manufacturing process. The strategy is implemented, and new statistical sampling of the finished product determines whether the strategy has been successful. If unsuccessful, a new strategy is implemented and the process is repeated.<sup>33</sup>

Implementation of statistical quality control requires statistical sampling or inspection of the end product. As explained above, the modern manufacturer tolerates a certain amount of variation in the final product within a range defined by the go/no-go limits. He calculates the variation in the final product by taking a statistical sample, measuring some characteristic of the product, and calculating the mean and standard deviation of that product. Ideally, the mean should equal the desired value of that characteristic, and the standard deviation (variation from the mean) should be small. For example, if a pipe manufacturer wishes to create pipes with a 2-inch internal diameter, he hopes that a statistical analysis of his pipes reveals a mean diameter of 2-inches with a small standard deviation. Now, let us assume that the manufacturer has already established a process capable of reliably producing 2-inch pipes with an acceptable standard deviation of 0.01 inches. If statistical sampling of the finished product reveals that the manufacturer is producing pipes with diameters that vary considerably (i.e., more than one or more standard deviations) from the mean of 2 inches, then the manufacturer has reason to believe that his manufacturing process is out of control.

Shewhart devised a method whereby the results of consecutive end product sampling can be plotted on a “quality control chart,” such that the manufacturer possesses a graphical representation of the control of his manufacturing process over time<sup>34</sup> A two-dimensional schematic diagram is presented below. The x-axis (horizontal axis) represents time, and the y-axis (vertical axis) represents the value of the physical characteristic being measured.



The quality control chart introduces the new concept of “control” or “action” limits, set within the go/no-go limits L1 and L2. Control limits are meant to represent the normal expected variation one would find if the manufacturing process was acting under control. Control limits are calculated as the mean desired value +/- some multiple of the standard deviation.<sup>35</sup> If in our above example, the pipe manufacturer wanted to detect variation greater than one standard deviation from the mean, he would set the control limits at 1.99

<sup>33</sup> See Sid Sytsima, *Quality and Statistical Process Control*. Online at <http://www.sytsma.com/tqmttools/ctlchtprinciples.html>.

<sup>34</sup> See Shewhart, *supra* note 29, at 4-8.

<sup>35</sup> See James O. Westgard, *QC—The Idea*. Online at <http://www.westgard.com/lesson11.htm>.

and 2.01 inches. Along the x-axis, the manufacturer would plot the mean diameter values measured from newly produced pipes. If the plotted points fall within the control limits, the manufacturer typically can be assured that his manufacturing process is under control.<sup>36</sup>

Control limits therefore serve as a warning sign that the manufacturing process may not reliably be producing items at or around the desired value. Shewhart explained as follows (refer to the above chart for clarification):

Statistical theory then stepped in (1924) with the concept of two action or control limits A and B that lie, in general within L1 and L2.... These limits are to be set so that when the observed quality of a piece of product falls outside of them, even though the observation be still within the limits L1 and L2, *it is desirable to look at the manufacturing process in order to discover and remove, if possible, one or more causes of variation that need not be left to chance.* In other words, whereas the limits L1 and L2 provide a means of gauging the product *already made*, the action limits A and B provide a *means of directing action toward the process* with a view to the elimination of assignable causes of variation so that the quality of the product *not yet made* may be less variable on the average.<sup>37</sup>

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[A]lthough the action limits A and B may lie within the tolerance limits L1 and L2, the product already produced and found by inspection to be within the limits L1 and L2 is still considered to conform, even if outside A and B. In other words, the action limits A and B do not apply as a gauge for product already made: their function is to call attention to evidence for believing that the manufacturing process includes assignable causes of variation in the quality that may give trouble in the future if they are not found and removed.<sup>38</sup>

Thus, when the data points plotted on the quality control chart approach the control limits, the manufacturer is alerted to the fact that there may be uncontrolled variation in the manufacturing process. In the context of statistical quality control, inspection and statistical sampling of the final product are not implemented to determine whether or not the final product is defective. Rather, they are implemented in order to monitor a manufacturing process that is known to reliably produce a quality product. Statistical quality control achieves the integration of production, specifications, and inspection, thereby eliminating the need for costly and inefficient end product inspection. It allows for manufacturers to shift their attention from end product inspection to identification of the causes of product deficiencies within the manufacturing process.

### Part III

The shift in focus from end-product testing to control of the manufacturing process remains the conceptual breakthrough of the quality control revolution. This breakthrough allowed manufacturers to dramatically increase the efficiency of their operations. W. Edwards Deming, a colleague of Shewhart, expanded the

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<sup>36</sup> *Id.*

concept of statistical quality control into “Total Quality Management (TQM),” a method of management that requires the entire organization to apply principles of statistical quality control.<sup>39</sup> Deming brought his TQM concept to post-war Japan and helped to transform its devastated manufacturing base into a global giant.<sup>40</sup>

Deming’s concept of integrating statistical quality control into the efficient management of a firm forms the link between the quality control chart and HACCP. The quality control chart serves to warn a manufacturer when the manufacturing process is uncontrolled. When statistical end-product sampling yields numbers that approach or exceed the control limit, the manufacturer must review the manufacturing process to find the sources of variability lurking within. If the manufacturer has not been monitoring the manufacturing process, then this review process will be difficult and costly. If, however, he has been monitoring and documenting key variables in the manufacturing process over time, then the manufacturer can simply compare his quality control charts with his manufacturing records in order to pinpoint the problem. TQM would therefore require routine monitoring of the manufacturing process.

In an efficient, integrated system, inspection of the manufacturing process becomes as important, if not more important than inspection of the end product. Deming explained: “Inspection is too late, ineffective, costly. When a lot of product leaves the door of a supplier, it is too late to do anything about the quality of the lot. Scrap, downgrading, and rework are not corrective action on the process. Quality comes not from inspection, but from improvement of the process. . . . In place of 100 per cent inspection should go improvement of the process and *elimination of inspection*.”<sup>41</sup>

How might a firm eliminate inspection? Well, if a manufacturer could identify the critical sources of variation in the final product, properly control those sources of variation within the manufacturing process, and document the control of the variation, then the manufacturer could be assured that the final product would be of uniform quality. In other words, the manufacturer’s control of critical points in the manufacturing process prevents any defects from occurring in the final product. The manufacturer may not eliminate end product inspection altogether, but he has essentially eliminated his reliance upon it.

The elimination of reliance upon end-product inspection can be illustrated through the example of aseptic canning. The manufacture of aseptically-sealed cans requires four steps: (1) the sterilization of the food product; (2) the transfer of the sterilized product into sterilized canning; (3) the sealing of the can in a sterile atmosphere, and (4) the gentle handling of the sealed can on contamination-free equipment.<sup>42</sup> In all of these steps, the hazard to be avoided in the end product is microbial contamination. Thus, the manufacturer will test the final product for microbial growth through the use of some biological assay; and will reject the product if the assay indicates a threshold amount of bacterial growth. The manufacturer will

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<sup>39</sup> Mouradian, *supra* note 26, at 92.

<sup>40</sup> *Id.* at 91; Deming was a highly celebrated figure in Japan. The Union of Japanese Scientists and Engineers instituted the Deming Prize, the country’s highest business award given to a company for the innovative use of statistical theory in organization, consumer research, product design and production. Additionally, in 1960 the Emperor of Japan rewarded Deming with the Second Order Medal of the Sacred Treasure, for his help in transforming the Japanese economy. See The W. Edwards Deming Institute, *Biography of W. Edwards Deming*. Online at <http://www.deming.org/theman/biography.html>.

<sup>41</sup> W. Edwards Deming, *Quality, Productivity, and Competitive Position* 22 (MIT, Center for Advanced Engineering Study 1982) (emphasis added).

<sup>42</sup> Keith Ito, *A Critical Appraisal of Aseptic Canning*, in *Proceedings of a Symposium on Newer Food Processing Technology*, *supra* note 17, at 24-26.

also test the final product for quality—e.g., taste, consistency, texture, color, etc.

Because end product testing is costly and inefficient, the manufacturer will try to prevent microbial growth through proper processing techniques—i.e., by heating the product at a specific temperature for a specific period of time, and by processing the product in a clean, sterile environment.<sup>43</sup> The manufacturer will experiment with different combinations of these two variables—time and heat—until he has established limitations upon these variables that ensure the final product’s sterility and quality. Rather than focus upon keeping microbial growth in the finished product within the “control limits,” the manufacturer will focus upon keeping the temperature and time of sterilization controlled within their “critical limits.” The manufacturer will also institute controls to maintain a sterile environment, establishing critical limits for the measurement of sterility in the plant.

The manufacturer will keep daily records of (a) the beginning and end of each sterilization step; (b) the temperatures achieved during sterilization; (c) the times when the machinery is cleaned and sterilized; and (d) other important occurrences (e.g., if production is stopped).<sup>44</sup> These records ensure that the manufacturer is monitoring the critical manufacturing steps, and provide a manufacturing history for the plant.

End product inspections of aseptically-sealed cans decrease in their importance and scope as they become ancillary to the daily inspections of the sterilization process.<sup>45</sup> Still, occasional end product inspections may be valuable as additional checks upon the product’s final quality. If the end product inspections reveal microbial growth exceeding the designated control limits, the manufacturer can refer back to his records to help identify the problem. Because the records provide a manufacturing history of the plant, the manufacturer can utilize the records as a troubleshooting tool in identifying the source of variation within the manufacturing process. Once the problem is identified, the manufacturer will institute new controls over the manufacturing process, such that he can continue to control quality through monitoring of critical control points in the manufacture, rather than through inspection of the final product.

The aseptic canning example demonstrates how integration of the three processes of specification, production and inspection result in an efficient quality control system that does not rely on end product inspections. The example is also a rough illustration of the seven basic principles of a HACCP plan. Below I introduce the basic HACCP regulatory requirements, and demonstrate how HACCP reformulates the concepts introduced by Shewhart and Deming.

HACCP step 1 requires manufacturers to conduct a hazard analysis; they must identify food hazards and implement a written HACCP plan for food hazards that are “reasonably likely to occur” during processing.<sup>46</sup> Step 2 requires manufacturers to identify within the HACCP plan the critical control points (CCPs)—the points in the manufacturing process where the identified food hazards can be minimized—and the measures

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<sup>43</sup> *Id.* at 26.

<sup>44</sup> *Id.* at 28-29.

<sup>45</sup> Dole’s manufacturing processes illustrate manufacturer reliance on control of the canning process: “All of the Dole systems have an instrument panel to continually monitor the temperatures at critical points. For example, the temperatures of the superheated steam going to the tunnels and to the cover sterilizer as well as the actual temperatures inside the sterilizers are continuously recorded. Moreover, temperatures in the filling and closing chambers and the product fill temperature are usually recorded.” W.P. Segner, *Aseptic Canning of Low-Acid Foods in Rigid Metal Containers*, in Proceedings of a Symposium on Newer Food Processing Technology, *supra* note 17, at 40.

<sup>46</sup> 21 C.F.R. §§ 120.7, 120.8, 123.6.

that will be taken to control the hazards.<sup>47</sup> The third step requires manufacturers to identify and establish critical limits, the outer boundaries in which physical, biological, or chemical parameters must remain in order to control the food hazards.<sup>48</sup>

In our example, a manufacturer of aseptically-sealed cans would identify microbial contamination as the hazard reasonably likely to occur during processing. The CCPs would include the stages at which the food is sterilized, the food is transferred to a can, the can is aseptically sealed, and the sealed can is safely handled. The manufacturer would control the temperature and time of sterilization, and/or the sterility of the environment, as each CCP required. Control would be established through the use of critical limits. For example, the manufacture may require that the machinery that sterilizes the food achieve and maintain a temperature of at least 200 degrees F for at least 30 seconds.

HACCP steps 4, 6 and 7—establishing monitoring, record-keeping and verification procedures—ensure the proper day-to-day functioning of the manufacturing process. Manufacturers must maintain records documenting the ongoing application of the HACCP; this requires written proof that the processor is monitoring the critical control points and critical limits, i.e., the actual recording of times, temperatures, and other measurements required by the HACCP plan.<sup>49</sup> Furthermore, the food processors must verify that the HACCP plan is being implemented properly. Trained individuals must review the company’s HACCP records and consumer complaints, check the calibration of process monitoring instruments, and, when necessary, conduct periodic end-product or in-process testing.<sup>50</sup> Because scientific knowledge is always expanding, the food processor must also validate its HACCP plan annually; if the food processor had earlier concluded that no hazards were present and no HACCP plan was needed, it must reassess its earlier hazard analysis whenever there are any changes that could “reasonably affect” whether a food hazard now exists.<sup>51</sup>

Under these HACCP steps, the manufacturer of aseptically-sealed cans would monitor the food sterilization equipment, and record the temperatures and times of sterilization at regular intervals throughout the day. Periodically, the manufacturer would re-calibrate the equipment’s thermometer, in order to ensure that the temperature measurements continue to be precise and accurate, and engage in end-product microbial testing of the finished food product. Finally, the manufacturer would continuously keep himself informed regarding the latest scientific and technological development in the field of aseptic canned food production. On an annual basis, he would review his HACCP plan and make any changes necessary to ensure the safety of his finished food product.

The final HACCP step (step 5) requires manufacturers to establish corrective actions. Manufacturers must include within their HACCP plans corrective actions for situations in which a deviation from a critical limit occurs—e.g., when sterilization machinery does not maintain the proper temperature.<sup>52</sup> These plans should ensure that any injurious product is withheld from the stream of commerce and that the cause of the deviation is corrected.<sup>53</sup> Should a deviation occur for which there is no plan, the manufacturer must quarantine the

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<sup>47</sup> 21 C.F.R. §§ 120.7(a)(3), 120.7(a)(5), 123.6(c)(2).

<sup>48</sup> See 21 C.F.R. §§ 120.3(e), 123.3(c).

<sup>49</sup> See 21 C.F.R. §§ 120.11(a)(2), 120.12, 123.8(a)(3), 123.9.

<sup>50</sup> See 21 C.F.R. §§ 120.11(a)(1), 123.8(a)(2).

<sup>51</sup> See *id.* Such changes may include changes in the source of raw materials or the intended use of the finished product by consumers.

<sup>52</sup> See 21 C.F.R. §§ 120.8(b)(5), 120.10, 123.6(c)(5), 123.7

<sup>53</sup> See 21 C.F.R. §§ 120.10(a), 123.7(b).

potentially injurious product; determine whether the food product meets the safety criteria for distribution; and take appropriate action to ensure that any injurious product does not reach consumers and that the cause of the deviation is corrected.<sup>54</sup> Anytime the manufacturer takes corrective actions, the actions must be documented.<sup>55</sup> Importantly, when a deviation occurs for which there is no plan, the manufacturer must reassess the HACCP plan, and make any necessary modifications to the plan; this requirement ensures that when unexpected deviations occur, the manufacturer will reassess and rework the safety and quality controls it has built into the system.<sup>56</sup>

Thus, the 7 principles of HACCP essentially reiterate the lessons of Shewhart and Deming in a different form. Specifically, HACCP directs manufacturers not to focus upon end product inspection, but rather to focus primarily upon the manufacturing process. FDA has chosen to adopt HACCP for foods at high risk for microbial contamination out of recognition that end-product testing is often an ineffective means for preventing both the occurrence of hazards in the final food product and the distribution of hazardous food to consumers.<sup>57</sup> HACCP may have been borne from statistical concepts and managerial theories that emphasized efficiency and economic benefits, but it has been adopted as a regulatory tool by FDA for its ability to protect the public health.<sup>58</sup> For the remainder of this paper, I discuss the application of HACCP as a preventative measure against microbial contamination, noting the advantages of this effective regulatory tool.

## Part IV

Although FDA did not nominally adopt HACCP as a regulatory tool until the mid 1990s, HACCP principles served as the framework for FDA's regulation of low-acid canned foods and acidified foods in the 1970s. These regulations resulted from a 1971 petition to the FDA by the National Canners Association ("NCA"), urging the agency to adopt good manufacturing practices for low-acid foods in "hermetically sealed containers which are processed by heat either before or after being sealed in the container."<sup>59</sup> The NCA (now the National Food Processors Association) was spurred into action by several outbreaks of botulism due to consumption

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<sup>54</sup> See 21 C.F.R. §§ 120.10(b), 123.7(c).

<sup>55</sup> See 21 C.F.R. §§ 121.10(c), 123.7(d).

<sup>56</sup> See 21 C.F.R. §§ 120.10(b), 123.7(c).

<sup>57</sup> "Microbiological tests are seldom effective for monitoring due to their time-consuming nature and problems with assuring detection of contaminants. Physical and chemical measurements are often preferred because they are rapid and usually more effective for assuring control of microbiological hazards. For example, the safety of pasteurized milk is based upon measurements of time and temperature of heating rather than testing the heated milk to assure the absence of surviving pathogens." National Advisory Committee on Microbiological Criteria for Foods, *Hazard Analysis and Critical Control Point Principles and Application Guidelines* (Aug. 14, 1997). Online at <http://www.cfsan.fda.gov/~comm/nacmcfp.html>.

<sup>58</sup> "The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of . . . our nation's food supply[.] . . . The FDA is also responsible for advancing the public health by helping to speed innovations that make . . . foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use . . . foods to improve their health." Food and Drug Administration, *FDA Mission Statement*. Online at <http://www.fda.gov/opacom/morechoices/mission.html>.

<sup>59</sup> Manufacture and Processing of Canned Foods, 36 Fed. Reg. 21688 (Nov. 12, 1971).



of improperly processed canned foods.<sup>60</sup> In 1971, botulism toxin in soup packed by Bon Vivant caused one death and one severe illness, prompting coordinated efforts between NCA and FDA to recall remaining cans and notify consumers.<sup>61</sup> The canned food industry needed some way to reassure the public that their products were safe; the industry concluded that it could effectively subvert the negative publicity and fear arising from the Bon Vivant episode by proposing regulations that controlled for botulism.<sup>62</sup>

Botulism is a paralytic illness caused by a neurotoxin produced by the bacteria *Clostridium botulinum*.<sup>63</sup> The bacteria can only survive in an anaerobic (oxygen-free) environment, such as is found in canned foods.<sup>64</sup> Food processors may prevent botulism by heat sterilization, thereby inactivating the bacterial spores.<sup>65</sup> Should the heat treatment not inactivate all the spores, processors may further inhibit bacterial growth by creating an acidic environment having a pH less than 4.6.<sup>66</sup> Furthermore, decreasing the water activity of the food by adding salt also inhibits bacterial growth, by decreasing the amount of water available to bacteria.<sup>67</sup> Low-acid canned foods—i.e., foods “with a finished equilibrium pH greater than 4.6 and a water activity ( $a_w$ ) greater than 0.85”<sup>68</sup>—harbor anaerobic environments that, when not properly heat sterilized, lack the proper acidity and water activity to prohibit the growth and reproduction of the deadly *C. botulinum* bacteria.

Therefore, NCA proposed rulemaking that would allow FDA to more effectively regulate the manufacture of low-acid foods and prevent botulism. NCA’s proposed rules required low-acid food processors: (1) to file with the FDA forms specifying, *inter alia*, the sterilization times and temperatures to be used during processing; (2) to equip “retort equipment”—machinery used for heat processing canned foods—with temperature recording devices; (3) to train and certify retort operators; (4) to “code” all containers for purposes of identification during the product’s sale and distribution; (5) to record and certify certain information, such as the product, the code number, the retort number, and sterilization times and temperatures; (6) to inspect container closures; and (7) to report all instances of under-processing and spoilage.<sup>69</sup> The proposed rules also contained detailed depictions of manufacturing equipment, accompanied by recommended or required specifications for the equipment.<sup>70</sup> Finally, the proposed rules required low-acid food processors to register with the FDA,<sup>71</sup> and upon demand of an FDA employee, to “permit the inspection and copying by such employee of the processing records...to verify that adequate processing and coding of such low-acid food

<sup>60</sup> Food and Drug Administration, U.S. Dept. of Agriculture, *U.S. Food Safety System Country Report. Annex II Precaution in U.S. Food Safety Decisionmaking*, at Paragraph 69 (2000). Online at <http://www.foodsafety.gov/~fsg/fssyst4.html>.

<sup>61</sup> Edward Dunkelberger, *The Statutory Basis for the FDA’s Food Safety Assurance Programs: From GMP, to Emergency Permit Control, to HACCP*, 50 Food & Drug L. J. 357, 364-65 (1995).

<sup>62</sup> *Id.* at 366.

<sup>63</sup> Centers for Disease Control and Prevention, Dept. of Health and Human Services, *Disease Listing, Botulism, General Information*. Online at [http://www.cdc.gov/ncidod/dbmd/diseaseinfo/botulism\\_g.htm](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/botulism_g.htm); the ability of botulism toxin, or “Botox”, to prevent muscle contraction explains its usefulness as a popular cosmetic injection. Food and Drug Administration, *Botox Cosmetic: A Look at Looking Good*, FDA Consumer Magazine (July-August 2002). Online at [http://www.fda.gov/fdac/features/2002/402\\_botox.html#illustration](http://www.fda.gov/fdac/features/2002/402_botox.html#illustration).

<sup>64</sup> World Health Organization, *Fact Sheet No. 270. Botulism*. Online at <http://www.who.int/mediacentre/factsheets/who270/en/>.

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

<sup>67</sup> Food and Drug Administration, *Foodborne Pathogenic Microorganisms and Natural Toxins Handbook. Factors Affecting the Growth of Microorganisms in Foods*. Online at <http://www.cfsan.fda.gov/~mow/app3.html>.

<sup>68</sup> 21 C.F.R. § 113.3(n) (definition of low-acid foods).

<sup>69</sup> 36 Fed. Reg. at 21689-91.

<sup>70</sup> *Id.* at 21691-96.

<sup>71</sup> *Id.* at 21688.

was performed.”<sup>72</sup>

Failure to meet any of the proposed rule’s requirements would constitute “a prima facie basis for the immediate application of the emergency permit control provisions” of Section 404 of the Federal Food, Drug, and Cosmetic Act.<sup>73</sup> Section 404 applies to classes of foods found by FDA to be injurious to the public health when contaminated with micro-organisms, but for which there are no adequate means to determine whether or not the foods are in fact injurious due to microbial contamination prior to their interstate shipment; the statutory provision effectively allows FDA to prohibit the interstate shipment of such classes of food, unless food processors have obtained an emergency permit from the Agency.<sup>74</sup> Importantly, § 404 grants the Agency the power to condition the receipt and continued possession of the permit on the fulfillment of specified manufacturing controls, and to freely inspect any place of manufacture for violations of the conditions of the permit.<sup>75</sup> Thus, the threat of harsh regulatory actions would ensure compliance with NCA’s proposed regulations.

After evaluating the proposal and the comments, the FDA Commissioner decided that regulations should be immediately promulgated.<sup>76</sup> In November 1972, the Commissioner issued a tentative final order establishing minimum good manufacturing processes for heat-sterilized low-acid foods, soliciting comments on the tentative final order.<sup>77</sup> Two months later, in January 1973, the Agency adopted, in large part, NCA’s proposed regulations as its own.<sup>78</sup> Notably, FDA abandoned the requirement that food processors report to the Agency all instances of under-processing and spoilage.<sup>79</sup> In addition, the Agency temporarily set aside the provisions dealing with enforcement of the good manufacturing practices. FDA wrote, “Such regulations, including both the registration and record inspection provisions proposed by NCA and general procedural regulations with respect to the use of section 404, are presently being developed in order to establish an adequate enforcement mechanism.”<sup>80</sup>

In May 1973, FDA separately promulgated emergency permit regulations, consisting of general procedural regulations for section 404,<sup>81</sup> and regulations specific for low-acid canned foods.<sup>82</sup> The regulations required that (1) all current and future commercial processors of low-acid canned foods register with FDA and provide the Agency information “including but not limited to the processing method, type of retort or other thermal processing equipment, minimum initial temperature, time and temperature of processing sterilizing value ( $F_o$ ), or other equivalent scientific evidence of process adequacy, critical control factors affecting heat penetration, and source and date of the establishment of the process for each such low-acid

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<sup>72</sup> *Id.* at 21688, 21689.

<sup>73</sup> *Id.* at 21688.

<sup>74</sup> 21 U.S.C. § 344.

<sup>75</sup> *Id.*; Note that § 404 embodies the lessons of statistical quality control. It discounts the effectiveness of end-product inspection and mandates that manufacturers instead control their manufacturing processes.

<sup>76</sup> Low-Acid Foods in Hermetically Sealed Containers, 37 Fed. Reg. 24117 (Nov. 14, 1972).

<sup>77</sup> *Id.* at 24118.

<sup>78</sup> Part 128b—Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, 38 Fed. Reg. 2398 (Jan. 24, 1973).

<sup>79</sup> See Part 90—Emergency Permit Control. Manufacturing and Processing of Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, 38 Fed. Reg. 12716, 12717 (Paragraph 10) (May 14, 1973).

<sup>80</sup> 38 Fed. Reg. at 2398.

<sup>81</sup> 38 Fed. Reg. at 12720. (FDA issued a correction at 38 Fed. Reg. 14174 (May 30, 1973), final regulations at 39 Fed. Reg. 3748 (Jan. 29, 1974), and an amendment at 39 Fed. Reg. 11876 (Apr. 1, 1974)).

<sup>82</sup> 38 Fed. Reg. at 12716.

food in each container size”;<sup>83</sup> (2) all operators of critical processing systems be under the supervision of a trained manager;<sup>84</sup> (3) food processors report instances of spoilage or process deviation where the lot of food had entered distribution, in whole or in part;<sup>85</sup> (4) food processors establish an effective recall plan;<sup>86</sup> (5) processors systematically retain and review records of processing, deviations in processing, and inspections, and permit the FDA to inspect and copy such records;<sup>87</sup> and (6) food processors submit, upon request, “any information concerning processes and procedures which is deemed necessary by the Food and Drug Administration to determine the attainment of commercial sterility.”<sup>88</sup> Should the food processor violate the above regulations, the Agency could determine that the processor needed an emergency permit to resume manufacturing—the issuance and retention of the permit, of course, being dependent upon future compliance with the regulations.<sup>89</sup>

In 1976, FDA proposed some changes to the low-acid canned food regulations, responding to questions regarding the scope and details of the regulations.<sup>90</sup> One issue regarded the applicability of the regulations to foods with a water activity ( $a_w$ ) greater than 0.85, in which spore-forming microbes resistant to heating could be inhibited through the control of water activity, the use of salt or other chemicals, or by innate characteristics of the food itself. FDA, lacking scientific evidence as to the safety of such food processing, declined to exempt such foods from the regulations for the time being.<sup>91</sup> However, the Agency did propose amendments to the regulations requiring the control of such “critical factors” as water activity in order to ensure the safety of the food.<sup>92</sup> Another significant proposed change involved a requirement that food processors maintain a separate file of all manufacturing deviations where the “minimum requirements set by the scheduled process”—i.e., the control limits—were not met.<sup>93</sup> The stated purpose of the change was to allow FDA and the manufacturer to readily identify any food product that may have been improperly processed.<sup>94</sup>

Also in 1976, FDA decided to separately regulate “acidified foods,” which had previously been included in the proposed low-acid food regulations.<sup>95</sup> Acidified food includes vegetables, fruits, and other foods with a water activity greater than 0.85 that are acidified at or below a pH of 4.6 in order to prevent the growth of *C. botulinum* bacteria.<sup>96</sup> Thus, acidified foods have a pH at or below 4.6, whereas low-acid foods have a pH higher than 4.6. This regulatory distinction accounts for the fact that *C. botulinum* growth is inhibited in acidic environments at or below a pH of 4.6; yet, FDA chose to regulate acidified foods in a manner similar to low-acid foods, because improper control over the acidity in acidified foods could render them

<sup>83</sup> *Id.* at 12717-18 (§§ 90.20(c)(1), (2)).

<sup>84</sup> *Id.* at 12718. (§ 90.90(g)).

<sup>85</sup> *Id.* at 12718. (§§ 90.90(d), (e)).

<sup>86</sup> *Id.* at 12718. (§ 90.90(f)).

<sup>87</sup> *Id.* at 12718. (§ 90.90(h)).

<sup>88</sup> *Id.* at 12718. (§ 90.90(c)(3)(ii)).

<sup>89</sup> 38 Fed. Reg. at 20-21 (§§ 90.1-90.7).

<sup>90</sup> Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers. Good Manufacturing Practice, 41 Fed. Reg. 30444 (July 23, 1976).

<sup>91</sup> *Id.*

<sup>92</sup> *Id.* at 30447 (proposed 128b.3(f)).

<sup>93</sup> *Id.* At 30446, 30457 (proposed 128b.9).

<sup>94</sup> *Id.* At 30446.

<sup>95</sup> *See id.* at 30444.

<sup>96</sup> *See* 21 C.F.R. § 114.3(b); the term “acidified foods” now includes pickled and fermented foods, whereas when the regulations were first proposed, such terms were separately defined. *See* Pickled, Fermented, and Acidified Foods. Good Manufacturing Practice, 41 Fed. Reg. 30457 (July 23, 1976).

just as dangerous as improperly processed low-acid foods. FDA proposed that food processors implement processing and recordkeeping controls similar to those for low-acid canned foods in order to ensure that the finished equilibrium pH of acidified foods not exceed 4.6.<sup>97</sup> Similarly, FDA proposed emergency permit control regulations for acidified foods, analogous to those for low-acid foods.<sup>98</sup>

The emergency permit control regulations, including the general provisions (subpart A) and the provisions specific to low-acid foods (subpart B), were finalized in 1977.<sup>99</sup> These provisions are currently codified at 21 C.F.R. §§ 108.3-108.19 (general provisions) and 108.35 (low-acid foods). The emergency permit control regulations for acidified foods (subpart B) were finalized in 1979, and are currently codified at 21 C.F.R. § 108.25.<sup>100</sup> Also in 1979, the FDA finalized its good manufacturing practice provisions for low-acid foods and acidified foods.<sup>101</sup> Those provisions are currently codified at 21 C.F.R. Parts 113 (low-acid foods) and 114 (acidified foods). Subsequent to the finalization of the regulations in 1977 and 1979, FDA has periodically made minor revisions, but the core provisions deriving from the NCA petition remain intact.<sup>102</sup>

With all of the key regulatory provisions finalized, one can identify the essential features of a HACCP plan. Take, for example, the regulations for low-acid foods. The hazard addressed by the regulations is botulism. The critical factors in the manufacture of low-acid foods that the regulations seek to control include pH (acidity), water activity, storage conditions (anaerobic atmosphere and ambient temperature) and temperature (degree and time of heating necessary for commercial sterility).<sup>103</sup> The critical control points are those places in the manufacturing process where the critical factors can be controlled, which include the retorts, the aseptic processing and packaging systems, and other systems that a manufacturer may use. The regulations provide detailed requirements for the manufacturing equipment, mandating, e.g., that retorts be equipped with mercury-in-glass thermometers, temperature-recording devices, pressure gages, and steam controllers.<sup>104</sup> The regulations also require control over the container filling and closure processes,<sup>105</sup> as well as the procurement of suitable raw materials.<sup>106</sup>

Because the low-acid food regulations nominally do not require HACCP compliance, they never mention the term “critical limit.” Instead, the concept of critical limits is embodied within the requirement for a “scheduled process” or HACCP-like plan that specifies “the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility.”<sup>107</sup> For example, one such scheduled process is the “minimum thermal process”—i.e., the application of heat “for a period of

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<sup>97</sup> 41 Fed. Reg. at 30460-61 (§§ 128g.7 and 128g.8).

<sup>98</sup> Pickled, Fermented, and Acidified Foods. Emergency Permit Control, 41 Fed. Reg. 30442 (July 23, 1976).

<sup>99</sup> Part 108—Emergency Permit Control, 42 Fed. Reg. 14334 (Mar. 15, 1977).

<sup>100</sup> Part 108—Emergency Permit Control. Acidified Foods. Final Rule, 44 Fed. Reg. 16204 (Mar. 16, 1979).

<sup>101</sup> Part 113—Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers. Current Good Manufacturing Practice. Final Rule, 44 Fed. Reg. 16209 (Mar. 16, 1979); Part 114—Acidified Foods. Current Good Manufacturing Practice. Final Rule, 44 Fed. Reg. 16230 (Mar. 16, 1979).

<sup>102</sup> The regulations, published in 21 C.F.R., note the “source” or Federal Register publication from which they are derived. Please refer to the relevant provision in order to identify and locate amendments made subsequent to the publication of the 1977 and 1979 final rules.

<sup>103</sup> 21 C.F.R. § 113.3(f) defines “critical factor” and § 113.3(e) defines “commercial sterility”. For a discussion of the critical factors, see above text, or refer to 44 Fed. Reg. at 16209-10.

<sup>104</sup> 21 C.F.R. § 113.40(a)-(f); a retort is defined as “any closed vessel or other equipment used for the thermal processing of foods. 21 C.F.R. § 113.3(q).

<sup>105</sup> 21 C.F.R. §§ 113.60, 113.81(c), (d).

<sup>106</sup> 21 C.F.R. § 113.81(a).

<sup>107</sup> 21 C.F.R. § 133.3(r).

time and at a temperature scientifically determined to be adequate to ensure destruction of microorganisms of public health significance.”<sup>108</sup> This process must be “established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations,” and must take into account the “type, range, and combination of variations encountered in commercial production.”<sup>109</sup> Furthermore, when addition of a solute such as salt is required for the safe processing of low-acid foods, the critical limit of equilibrium water activity of the finished product must be specified in the scheduled process devoted to water activity and carefully controlled.<sup>110</sup>

As with HACCP plans, the low-acid food regulations require monitoring of the critical limits and documentation that critical variables in the manufacturing process have not exceeded their critical limits. As noted above, food processors must install retorts equipped with thermometers and temperature recording devices, allowing the temperature to be monitored. Processors must also employ inspectors, operating under the supervision of trained individuals,<sup>111</sup> to regularly observe container closures for gross closure defects.<sup>112</sup> Containers must be coded to allow processors to track the manufacture and distribution of individual cans throughout their entire lifecycle.<sup>113</sup> An extensive list of parameters that must be monitored and documented is provided at 21 C.F.R. § 113.100. Records pertaining to the establishment of the scheduled process and incubation tests necessary to validate the process must be permanently retained.<sup>114</sup> Other records must be maintained for at least 3 years following the date of manufacture.<sup>115</sup> Such records must be made available to the FDA upon request for inspection and copying, pursuant to the emergency permit regulations.<sup>116</sup>

The low-acid food regulations, like HACCP, also require that deviations in processing or loss of control over critical factors be documented and corrected, and that the corrections be documented.<sup>117</sup> FDA requires food processors to quarantine food manufactured by a potentially faulty process, and either reprocess the food, destroy the food, or evaluate the food to ensure its safety for public consumption; when process deviations exceed the critical limits (i.e., “the minimum requirements of the scheduled process”), food processors must take corrective action.<sup>118</sup> Sometimes, corrective action may entail a recall. The emergency permit regulations require the food processor to “have prepared and in his files . . . plans for effective recalls of any product that may be injurious to health; for identifying, collecting, warehousing, and controlling the product; for determining the effectiveness of such recall; for notifying [FDA] of any such recall; and for implementing such recall program.”<sup>119</sup>

Importantly, the low-acid food regulations differ from HACCP in the absence of an explicit requirement that the scheduled processes or quality control system be periodically verified. Presumably, FDA could interpret its existing regulations in such a manner as to include a verification requirement; for example, the Agency

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<sup>108</sup> 21 C.F.R. § 133.3(o).  
<sup>109</sup> 21 C.F.R. § 113.83.  
<sup>110</sup> 21 C.F.R. § 113.81(f).  
<sup>111</sup> 21 C.F.R. § 113.10.  
<sup>112</sup> 21 C.F.R. § 113.60(a).  
<sup>113</sup> 21 C.F.R. §§ 113.60(c), §113.100.  
<sup>114</sup> 21 C.F.R. § 113.83.  
<sup>115</sup> 21 C.F.R. §§ 113.100(e), 108.35(h).  
<sup>116</sup> 21 C.F.R. § 108.35(h).  
<sup>117</sup> 21 C.F.R. § 113.89.  
<sup>118</sup> *Id.*  
<sup>119</sup> 21 C.F.R. § 108.35(f).

could require such verification information as part of the scheduled processes that must be filed shortly after registration.<sup>120</sup> Alternatively, FDA could informally require such verification solely based on a threatened imposition of the emergency permit requirement. Notwithstanding these creative solutions, however, the regulations as promulgated currently do not impose a requirement that food processors routinely verify their scheduled processes. This absence potentially renders the low-acid food regulations less effective than HACCP in preventing foodborne microbial illness, because it allows food processors to assume the continued efficacy and safety of their scheduled processes, without any validating scientific evidence to support that assumption.

## Part V

HACCP is a means of industry self-regulation enforced via a threat of government action should the industry fail to regulate itself. The manufacturer identifies the hazards specific to his operations and develops a quality control plan sufficient to control those hazards. Should there be any indication that quality control is not being maintained, the manufacturer evaluates the current quality control plan and makes any necessary adjustments. Periodically, as a prophylactic measure, the manufacturer validates his quality control plan, to ensure that his smoothly running manufacturing process meets his goal of producing safe, quality goods. The manufacturer's analysis of his manufacturing process and HACCP plan are guided by his specific needs and goals, not by the specific mandates of regulators. The oversight of HACCP plans by regulators helps to ensure that manufacturers take seriously their responsibilities to their consumers and the public at large.

The low-acid and acidified foods regulations, in contrast, do not represent industry self-regulation. The FDA identified the relevant hazard (botulism) and crafted a series of regulations to prevent the occurrence of this hazard, even going so far as to identify the critical factors and critical control points that food processors must monitor and control. Given that the Agency possessed scientific evidence regarding how pH, temperature, and water activity affected the growth of *C. botulinum* in canned food, FDA's decision to mandate the control of these factors is entirely reasonable and appropriate.<sup>121</sup> However, for foods for which there are multiple potential hazards and multiple means of controlling those hazards, the promulgation of regulations that adequately address regulators' food safety concerns becomes much more difficult. Not all food processors will face the same hazards, and even if the hazards are the same, not all food processors will be able to employ the same solution and still maintain sufficient quality of the finished food product. Thus, where manufacturers of a certain category of food face diverse problems with respect to safety and quality, a regulatory model that embraces industry self-regulation like HACCP seems more appropriate and efficient, when compared to a more defined and circumscribed regulatory scheme as is found with low-acid and acidified foods.

FDA learned this lesson the hard way with respect to its regulation of good manufacturing practices for smoked fish. In 1969, the Agency proposed regulations in order to counter the threat of botulism associated with smoked fish products, concerned that "some processors base their manufacturing processes solely upon the appearance and acceptability of the finished product quality to consumers rather than on any specific or

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<sup>120</sup> 21 C.F.R. § 108.35(c)(2).

<sup>121</sup> See, e.g., Food and Drug Administration, *Foodborne Pathogenic Microorganisms and Natural Toxins Handbook. Factors Affecting the Growth of Some Foodborne Pathogens*. Online at <http://www.cfsan.fda.gov/~mow/factors.html>.

controlled processing parameters” that would minimize the production of botulism toxin.<sup>122</sup> The proposed rule required that smoked fish contain at least 3.5% salt, and be heated at 180°F or higher for at least 30 minutes, regardless of the species of fish being processed.<sup>123</sup> The Bureau of Commercial Fisheries, Department of the Interior, opposed the proposed rule on the basis that adequate time, temperature and salinity concentrations necessary to prevent botulism had not been determined for the various individual species of fish.<sup>124</sup> The Bureau’s concern was that a one-size-fits-all approach would subject some smoked fish products to over-processing, harming the quality of the final product. The FDA, in its final rule for smoked fish, granted fish processors another option of increasing the smoked fish’s salinity to 5.0%, and decreasing the temperature to 150°F (for 30 minutes), but otherwise allowed no variation from the two “TTS” (time-temperature-salinity) options.<sup>125</sup>

FDA rationalized that given the threat of botulism and the knowledge that certain TTS combinations sufficed to prevent botulism, it should err on the side of caution and apply its TTS requirements to all species of fish.<sup>126</sup> In the preamble to the proposed rule, FDA pledged that it would be receptive to scientific data that demonstrated alternate means of processing for any individual species of fish.<sup>127</sup> However, any individual food processor had little incentive to shoulder the costs of developing such species-specific scientific data and providing it to FDA, when all of its competitors could “free-ride” off of the information. Accordingly, some manufacturers of smoked fish simply implemented what they believed to be effective quality control measures and refused to comply with the regulations.

This brings us to the celebrated administrative law case of U.S. v. Nova Scotia Food Products Corp.<sup>128</sup> Nova Scotia Food Products Corp. (“Nova Scotia”), a processor of smoked whitefish, did not comply with the TTS regulations, claiming that to do so would result in an unmarketable product. Nova Scotia defended its actions upon the grounds that the regulations were invalid because (1) the regulations exceeded FDA’s delegated authority; (2) FDA relied upon undisclosed scientific data in promulgating the regulations, such that its decision to adopt the regulations was unsupported by the administrative record; and (3) there was no adequate statement setting forth the basis of its regulation, as required by the Administrative Procedure Act (“APA”), 5 U.S.C. § 553(c).<sup>129</sup>

The court rejected Nova Scotia’s first argument, finding within the Federal Food Drug and Cosmetic Act § 402(a)(4) sufficient authority to regulate microbial food hazards. Nova Scotia argued that the § 402(a)(4) prohibition against “food held under insanitary conditions whereby it may have become contaminated with filth” applied only to insanitary conditions in the manufacturing plant itself (i.e., “filth”); Nova Scotia contended that FDA’s regulation of microbial contamination *endemic* to the food product itself must proceed pursuant to the emergency permit provisions of § 404 in order to be a valid exercise of delegated authority.<sup>130</sup> The court, disregarding the plain language of § 402(a)(4) in favor of the Act’s legislative purpose of protecting

<sup>122</sup> Human Foods; Current Good Manufacturing Practice (Sanitation) in Manufacturing, Processing, Packaging or Holding. Smoked Fish, 34 Fed. Reg. 17176, 17177 (Oct. 23, 1969).

<sup>123</sup> *Id.* (§128a.1(d)); *Id.* at 17178 (§128a.7(d)(2)).

<sup>124</sup> *Id.* at 17176.

<sup>125</sup> Part 128a—Fish and Seafood Products. Subpart A—Smoked and Smoke-Flavored Fish, 35 Fed. Reg. 17401, 17402 (Nov. 13, 1970) (*see* § 128a.7(d)(2)).

<sup>126</sup> *Id.* at 17401.

<sup>127</sup> 34 Fed. Reg. at 17177.

<sup>128</sup> 568 F.2d 240 (2nd Cir. 1977).

<sup>129</sup> *Id.* at 243.

<sup>130</sup> *Id.* at 245-47.

public health, rejected the argument, noting that invalidation of the TTS regulations in this manner would require the invalidation of numerous regulations aimed at preventing microbial contamination of food.<sup>131</sup>

With respect to Nova Scotia's second and third arguments, the court agreed with the whitefish processor that failures in the notice-and-comment rulemaking procedures doomed the regulation. FDA did not keep a contemporaneous record consisting of data on which the Agency's decision-making was based; rather, after the Nova Scotia court proceedings commenced, FDA created a record consisting of comments received during the rulemaking process and scientific data the Commissioner claimed that he relied upon, but which were not disclosed to the public.<sup>132</sup> The court ruled that the lack of public disclosure of the scientific data denied interested parties of their opportunity to make *meaningful* comments; for without access to the data underlying the agency's actions, interested parties cannot make comments that are likely to persuade the Agency.<sup>133</sup> In other words, FDA's actions rendered ineffective the "comment" portion of notice-and-comment rulemaking. Furthermore, the court ruled that FDA failed to adequately state its basis and purpose of the TTS regulations by not addressing manufacturers' concerns that the regulations, as proposed, would render certain species of fish unmarketable.<sup>134</sup> Allowing such vital concerns to go unaddressed would promote, rather than prevent, arbitrary decision-making.

The Nova Scotia opinion is notable for the extent to which the court's decision appears to be influenced by its opinion of the administrative agency's policy decision. The court explicitly framed the procedural issues in the light of three key issues: "(1) whether, in the light of the rather scant history of botulism in whitefish, that species should have been considered separately rather than included in a general regulation which failed to distinguish species from species; (2) whether the application of the proposed T-T-S requirements to smoked whitefish made the whitefish commercially unsaleable; and (3) whether the agency recognized that prospect, but nevertheless decided that the public health needs should prevail even if that meant commercial death for the whitefish industry."<sup>135</sup> The court, contemplating these issues, concluded that FDA's response to the threat of botulism required a more nuanced approach than the imposition of one of two TTS schemes, either of which would render otherwise safe food unmarketable. The court wrote, "It is easy enough for an administrator to ban everything. In the regulation of food processing, the worldwide need for food also must be taken into account in formulating measures taken for the protection of health. In the light of the history of smoked whitefish to which we have referred, we find no articulate balancing here sufficient to make the procedure followed less than arbitrary."<sup>136</sup>

Thus, the court invalidated the TTS regulations on procedural grounds and, arguably, also on policy grounds. Following the Nova Scotia decision, FDA ceased enforcement of the regulations.<sup>137</sup> In 1983, FDA proposed a revocation of the TTS regulations, announcing that it was in the process of "developing data to support minimum T-T-S requirements", a project that "will take considerable time to complete."<sup>138</sup> The Agency decided for the time being to undertake the lengthy and complicated task of compiling TTS requirements on a species-by-species basis. Given the obvious costs of this method of regulation, the choice of HACCP

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<sup>131</sup> *Id.* at 246-48.

<sup>132</sup> *Id.* at 249-50.

<sup>133</sup> *Id.* at 252.

<sup>134</sup> *Id.* at 253.

<sup>135</sup> *Id.* at 250.

<sup>136</sup> *Id.* at 253.

<sup>137</sup> Smoked and Smoke-Flavored Fish; Current Good Manufacturing Practice. Proposed Rule, 48 Fed. Reg. 48836 (Oct. 21, 1983).

<sup>138</sup> *Id.*



and industry self-regulation became increasingly attractive.

## Part VI

In 1988, Congress appropriated funds to the National Oceanic and Atmospheric Administration (NOAA) of the Department of Commerce for the purpose of studying the implementation of a HACCP certification and seafood surveillance program. The National Marine Fisheries Service (“NMFS”) of NOAA subsequently recruited the National Academy of Sciences’ Institute of Medicine (“IOM”) to conduct the study.<sup>139</sup> The IOM report concluded that the diverse health risks associated with seafood best could be controlled through a regulatory system that addressed the various hazards on a geographically-restricted and/or species-specific basis, foregoing the “one size fits all” approach of the withdrawn TTS regulations. The authors wrote, “[T]his will require something other than organoleptically based inspection systems [e.g., visual inspection systems], which may be useful for quality control and grading but are essentially worthless for detecting and controlling health risks.”<sup>140</sup> Later, the authors concluded, “Postharvest control seems likely to be most readily achieved through an HACCP-based system focusing on cross-contamination, temperature control, and the effectiveness of handling and processing methods designed to inhibit or destroy microorganisms.”<sup>141</sup>

Years later, the FDA accepted the conclusion of the IOM and adopted HACCP as a regulatory tool to ensure the safety of fish and fish products. On January 28, 1994, FDA published its proposed HACCP seafood rule.<sup>142</sup> The final rule issued on December 18, 1995, with an effective date of 2 years from publication, December 18, 1997.<sup>143</sup> FDA’s reasons for adopting a HACCP regulatory system were varied and numerous, but perhaps none were as important as the lessons learned from the Nova Scotia case and its aftermath. That case brought to the forefront the difficulties inherent in the regulation of seafood—in particular the need for the FDA to craft individualized regulations that recognize and account for the broad variation inherent in the category of seafood. After Nova Scotia, it became clear that the courts would not allow the Agency to promulgate generally applicable seafood regulations, given the diversity among different types of seafood, their environments, and the hazards affecting the seafood effectively prohibited.

Thus, Nova Scotia placed an enormous burden on FDA, requiring the Agency in its regulations either to address individually the various hazards affecting seafood, or not to address the hazards at all. For concerned government officials, inaction was not an option, not only for the obvious public health reasons, but also for the economic reasons of shoring up consumer confidence in the safety and quality of seafood.<sup>144</sup> Perhaps inaction would have been a viable option had FDA’s existing regulatory framework been able to adequately protect consumers. However, FDA had been relying primarily upon periodic plant inspections and end-product testing as a means to ensure safety.<sup>145</sup> The Institute of Medicine reviewed FDA’s sampling

<sup>139</sup> Institute of Medicine, Committee on Evaluation of the Safety of Fishery Products, *Seafood Safety*, Page v (Farid E. Ahmed, Ed., National Academy Press 1991).

<sup>140</sup> *Id.* at 3.

<sup>141</sup> *Id.* at 17.

<sup>142</sup> Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products, 59 Fed. Reg. 4142 (Jan. 28, 1994).

<sup>143</sup> Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule, 60 Fed. Reg. 65095 (Dec. 18, 1995).

<sup>144</sup> See, e.g., Richard A. Williams, Jr., and David J. Zorn, Office of Scientific Analysis and Support, FDA, *Preliminary Regulatory Impact Analysis of the Proposed Regulations to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products* (Dec. 15, 1993). Online at <http://www.cfsan.fda.gov/~djz/cfudpria.txt>.

<sup>145</sup> *Id.*

procedures and found that they provided “relatively little protection to the public.”<sup>146</sup> The day-to-day realities of the seafood industry make lot sampling an imprecise and unreliable tool. The United States consumes a large volume of seafood, with over half of the seafood being imported from diverse regions of the world. As a result, an effective inspection-based system would require large sample sizes and diverse sampling plans to account for the various seafood species and hazards, requirements which could not be met with FDA’s limited resources.<sup>147</sup>

Furthermore, FDA’s inspection-based system employed testing that was destructive and very lengthy in nature. In other words, the testing often required the destruction of the sample seafood product, and laboratory evaluations might only be completed after the lot from which the sample originated had been eaten by consumers.<sup>148</sup> These disadvantages stemmed from the “reactive” regulatory posture of the FDA.<sup>149</sup> FDA did not provide the seafood industry with guidelines and warnings sufficient to prevent the occurrence of hazards in seafood. Instead, the Agency relied upon an inspection scheme to prevent *already hazardous* food from reaching the public. Should hazardous food reach the public, consumers likely would be without recourse, facing difficulty in tracing any resultant illness to seafood and to the particular firm that processed the hazardous seafood. FDA explained:

“The seafood industry differs from a large part of the food industry in that, except for certain branded fish products, almost all fresh and a large portion of frozen seafood is sold to the public unbranded or under brands that are not widely advertised and not generally recognized. Often, when fish or shellfish is offered for sale by a supermarket or restaurant, that product has been sourced from several suppliers in order to obtain a large enough quantity to meet consumer demand. Each supplier, in turn, may source from several processors for much the same reason. Likewise, each processor may receive raw material from several harvesters and possibly import it from one or more countries. For these reasons, these products lose their source identity and are marketed generically (exceptions being canned, frozen, and branded seafood). This subsequently makes it difficult for a supermarket or restaurant to discern the source of the product involved in a consumer complaint. As a result, some firms may not be adequately motivated to provide sufficient levels of safety. Thus, it may be argued that, for the most part, the tort system does not adequately compensate consumers for illnesses derived from the consumption of seafood.”<sup>150</sup>

Clearly, federal regulators believed that the pre-existing inspection system coupled with the tort system proved inadequate to deter regulatory violations, ensure the safety of consumers, and build consumer confidence in seafood products. Thus, regulatory inaction—an unfortunate by-product of the Nova Scotia decision—could not be continued indefinitely. However, the remaining option left open to FDA by Nova Scotia—species-specific and/or geographic region-specific regulations—raised the specter that the Agency could be bogged down interminably by the complexities of aquatic life. That FDA understood the magnitude of this potential regulatory burden is evident from the HACCP proposed rule. FDA wrote:

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<sup>146</sup> Institute of Medicine, *supra* note 139, at 283.

<sup>147</sup> *Id.* at 267.

<sup>148</sup> *Id.* at 268.

<sup>149</sup> *Id.* at 13.

“Ensuring the safety of seafood presents special challenges to both the industry that produces it and to Government agencies charged with protecting the public health. Seafood is unique in many respects. While often thought of as homogeneous in nature, seafood is actually a variety of products encompassing literally hundreds of species that have little in common other than an aquatic origin. Collectively, seafoods have perhaps the most diverse and complex microbiology of any food commodity.

“The range of habitats for edible species is also extraordinary and diverse ranging from cold to warm water, bottom dwelling to surface feeding, deep sea to near shore, and fresh water to saltwater. Fish are exposed to the bacteria and viruses that naturally occur in their environment as well as to those that enter the water through pollution. Chemicals, some of which are toxic to humans, can accumulate in fish as well. Fish can also accumulate natural toxins and parasites that are specific to marine animals. As a consequence, fish are subject to a wide range of hazards before harvest.”<sup>151</sup>

Microbial contamination, environmental pollution, bioaccumulation of toxins, hundreds of seafood species with diverse biological characteristics—if FDA were to promulgate TTS (or similar) regulations, it would need to account for all of these factors. With this in mind, one can understand why HACCP was such an attractive regulatory option for the Agency. HACCP shifts the burden of identifying and controlling for the numerous seafood hazards from the government to industry. HACCP makes seafood processors responsible for understanding the biology of the species being harvested, processed and sold, and using that information to establish sanitary procedures for delivering seafood from the aquatic environment to consumers.

The documentation and recordkeeping provisions of HACCP also decrease the burden on FDA’s inspection resources. HACCP replaces the “snapshot” inspections of the previous regulatory regime with a cumulative view of the processor’s operations over time, as revealed by the processor’s records. Thus, under HACCP, the daily burden of inspecting the cleanliness and effectiveness of the manufacturing system is shifted to the seafood processor, whereas FDA merely inspects the processor’s inspection process. As a result, FDA’s inspection actions become more effective and efficient, focusing upon the processor’s handling of critical control points—the steps at which hazards can best be controlled—over a long period of time. Faced with limited resources, the Agency can henceforth utilize its inspection resources in a cost-effective manner, targeting the most serious hazards first for inspection.<sup>152</sup>

Conceptually, HACCP shifts the burden placed on FDA by the Nova Scotia decision from the Agency to private industry. In practice, however, the shift is only partial. After all, how could FDA properly review a HACCP plan and oversee compliance with that plan if it remained ignorant of the various hazards affecting seafood? If FDA did not educate the seafood processors as to the potential hazards, how could the Agency ensure that ignorant processors were not simply declaring their products hazard free and shipping potentially hazardous food to consumers? Therefore, FDA does compile information regarding the potential hazards for various types of seafood and does provide this information to industry. FDA guidance documents identify potential hazards and provide recommendations for controlling such hazards.<sup>153</sup> However, industry bears the final responsibility for ensuring that hazards are identified and controlled for in an appropriate manner.<sup>154</sup>

<sup>152</sup> See 60 Fed. Reg. at 65104 (FDA’s response to comment 14).

<sup>153</sup> See, e.g., Food and Drug Administration, *Fish and Fisheries Products Hazards and Control Guidance*. (Third Edition, June 2001). Online at <http://www.cfsan.fda.gov/~comm/haccp4.html>.

<sup>154</sup> See 60 Fed. Reg. at 65104 (FDA’s response to comment 15).

Therefore, HACCP represents a system of industry self-regulation encompassed within a larger federal regulatory framework. In this regard, HACCP also represents an innovation over past methods of hazard regulation. Unlike the low-acid canned foods regulations discussed above, the HACCP regulations dictate no criteria or parameters that food processors must meet in order to be in compliance with good manufacturing practices. There are no specific regulations regarding minimum temperature settings, machinery specifications, retorts, pressure gauges, or temperature-recording devices—only a method or set of guidelines that must be followed in order to ensure food safety.

## Part VII

HACCP properly should be characterized as a method of regulation, rather than as a body of regulations. It represents a commitment to the statistical quality control methods described by Shewhart and Deming decades ago, and eagerly adopted by post-war Japanese manufacturers. Thus, beyond the advantages already discussed, the seafood HACCP program confers upon firms the efficiency and economic benefits derived from statistical quality control.

In particular, HACCP offers seafood processors a comprehensive system from which to operate their businesses. This feature mitigates the costs associated with knowledge of and compliance with complex regulations promulgated by multiple regulatory bodies. Indeed, the regulation of seafood can only be described as divided and fractured. The FDA plays the primary role in establishing and enforcing regulatory limits for seafood, in order to ensure seafood product safety. The Environmental Protection Agency (EPA) assists FDA by identifying the range of harmful residual chemical contaminants that are likely to accumulate in seafood.<sup>155</sup> FDA also coordinates the National Shellfish Sanitation Program (NSSP), a voluntary program comprised of federal officials (e.g., FDA), state agencies, and private industry. Under NSSP, federal, state and private parties work together to establish a uniform body of guidelines and standards regarding shellfish to be enforced by state regulatory agencies. FDA bears responsibility for setting the standards and ensuring state compliance with the NSSP standards.<sup>156</sup> Furthermore, the National Marine Fisheries Service (NMFS) provides a voluntary (fee-for-service) seafood inspection program, which surveys firms' compliance with applicable federal regulations and certifies firms' use of official marks such as "U.S. Grade A" and "Processed Under Federal Inspection (PUFI)".<sup>157</sup> NMFS used to run a voluntary HACCP certification program, but with FDA's adoption of seafood HACCP regulations, NMFS converted this program into one that helps companies comply with HACCP.<sup>158</sup>

HACCP has not eliminated the fractionated regulation of seafood, (although it has rendered the NMFS voluntary program redundant). But HACCP does provide an overarching concept under which one can integrate these diverse aspects of seafood regulation. For example, a food processor must identify within its HACCP plan food safety hazards that are "reasonably likely to occur", including environmental factors such as natural toxins, chemical contaminants, and pesticides.<sup>159</sup> Furthermore, HACCP plans must be

<sup>155</sup> See Institute of Medicine, *supra* note 139, at 287.

<sup>156</sup> Food and Drug Administration, *National Shellfish Sanitation Program. Guide for the Control of Molluscan Shellfish* 2003. Online at <http://www.cfsan.fda.gov/~ear/nss2-toc.html>; Institute of Medicine, *supra* note 139, at 293.

<sup>157</sup> See USDC Seafood Inspection Program, online at <http://seafood.nmfs.noaa.gov>.

<sup>158</sup> U.S. Dept. of Commerce, Office of Inspector General, *NMFS Seafood Inspection Program Should Be Divested* (Sept. 1998). Online at <http://www.oig.doc.gov/oig/reports/1998/NOAA-STL-09607-01-09-1998.pdf>.

<sup>159</sup> 21 C.F.R. § 123.6(c).

specific to each kind of seafood product processed, including shellfish.<sup>160</sup> The HACCP seafood regulations include, as an “augmentation” to the general HACCP regulations, a subpart specific to the processing of molluscan shellfish “where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.”<sup>161</sup> This special subpart refers to the types of activities regulated by states under the NSSP. The NSSP’s “Model Ordinance”—the minimum requirements states must meet in regulating interstate commerce of molluscan shellfish—requires shellfish dealers to adopt HACCP plans.<sup>162</sup> Thus, the regulatory flexibility encompassed within the HACCP concept allows for a streamlining and unification of federal regulation.

Another benefit of HACCP is the ability of the United States to harmonize its seafood regulations with those of other countries. The 1995 final rule noted that, at that time, Canada had already implemented a HACCP system, and the EU had issued directives moving towards a HACCP system.<sup>163</sup> In a 1998 report written in association with the Food and Agricultural Organization (FAO) of the United Nations, the author noted:

“The use of HACCP in the seafood industry has taken on a global perspective in the production of fish and fishery products (Lima dos Santos and Sophonphong 1998). They report the results of an FAO survey that categorized the status of countries and the seafood industries in those countries in adopting seafood HACCP procedures. Countries whose governments and seafood industries which have adopted or decided to introduce seafood HACCP include Canada, Uruguay, Brazil, Chile, Ecuador, Australia, New Zealand, Thailand, Iceland, United States and more recently Argentina, Peru, Ireland, Cuba, Morocco, Norway, Sri Lanka, Vietnam and Bangladesh. A second group consists of countries whose governments have taken unilateral initiatives to introduce HACCP via regulations with limited success and cooperation between the regulatory authorities and the seafood industry. These countries include Mexico, Venezuela, and many member countries of the European Union, for example Italy, Germany and France. In a third group of countries, the private sector is taking the lead in voluntarily trying to introduce HACCP-based programmes regarding seafood export production. These include Madagascar, Venezuela, Honduras, Tunisia, Myanmar and Portugal. A final group consists of countries where governments have decided to apply HACCP but have not yet defined the process, including Japan, Russia and China. Remaining countries where the status of seafood HACCP is unclear include Pakistan, South Korea, Iran, Colombia, Panama, some East and Central European countries and most African States.”<sup>164</sup>

Although the details of the various countries’ HACCP regulations may vary, the fact that so many countries have gravitated towards a similar system significantly reduces the compliance costs of seafood processors that import their food to multiple nations. HACCP may operate, therefore, as a mechanism to encourage free trade between nations that have adopted the system, and as a trade barrier to those nations with less strict standards.<sup>165</sup> Furthermore, for U.S. companies that export seafood products to other countries with HACCP requirements, a mandatory U.S. HACCP requirement allows these companies to maintain their market share in foreign markets.<sup>166</sup>

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<sup>160</sup> 21 C.F.R. § 123.6(b).

<sup>161</sup> 21 C.F.R. § 123.20; Subpart C (21 C.F.R. §§ 123.20, 123.28) pertains to raw molluscan shellfish.

<sup>162</sup> National Shellfish Sanitation Program, *supra* note 156, at Chapter I, @.02.

<sup>163</sup> 60 Fed. Reg. at 65105.

<sup>165</sup> *Id.*

<sup>166</sup> 60 Fed. Reg. at 65102.

## Part VIII

As the preceding sections of this paper have demonstrated, the adoption of HACCP and HACCP-like systems benefits manufacturers, regulatory agencies, and consumers. However, HACCP is not problem-free. HACCP may significantly reduce the regulatory burden on federal regulatory agencies, but this reduction occurs at the expense of the regulated industry. Many of those who commented on the seafood final rule argued that compliance costs would make business unprofitable for small seafood processors, especially in the case of “economically-strapped, old family enterprises that support an often fragile local economy.”<sup>167</sup> Whereas it might be relatively cheap to monitor critical control points and properly document critical measurements, the costs to businesses of informing themselves of the various hazards properly applicable to their seafood products, developing an adequate HACCP plan, and training their employees could prove to be quite substantial. FDA acknowledged these costs, but determined that they were necessary if the public health protection purpose of the HACCP rules was to be fully implemented and respected. The Agency noted that its guidance documents, in conjunction with HACCP programs established by trade associations and other organizations, would serve to significantly reduce costs to small businesses.<sup>168</sup>

One potential consequence of the costs and other difficulties (perceived or actual) in transitioning to a HACCP quality control system is a conscious decision by seafood processors simply not to comply with HACCP, or to only make minor changes when major changes are needed. Alternatively, such processors may attempt to comply with HACCP, but find themselves financially unable to do so or unaware of all the material hazards and remedial controls affecting their seafood products. The ultimate result of these scenarios would be noncompliance with the regulations. Indeed, FDA’s compilation of data regarding HACCP compliance indicates a significant lack of compliance among seafood processors. FDA data for fiscal year 2003 indicates that 18% of the inspected domestic firms and 33% of inspected foreign firms that needed a HACCP plan did not have one. Furthermore, of firms with plans, substantial numbers failed to adequately identify within their plans all relevant hazards (13% domestic, 27% foreign), critical control points (14% domestic, 27% foreign), critical limits (18% domestic, 40% foreign), monitoring procedures (21% domestic, 36% foreign), and corrective actions (11% domestic, 18% foreign). Also, many firms failed to adequately implement HACCP monitoring procedures (24% domestic, 29% foreign) and keep adequate monitoring records (27% domestic, 44% foreign).<sup>169</sup> These numbers suggest that the informational and financial burdens imposed on industry by HACCP detract are quite difficult for some firms to meet, resulting in substantial noncompliance.

The data also illustrate a basic problem with industry self-regulation, namely that certain industry members might fail to adequately regulate themselves, for one reason or another. Of course, noncompliance is a problem that accompanies any regulatory system. However, one issue specific to the seafood HACCP system is whether firms have enough scientific expertise or enough accessibility to such expertise in order to identify and control for all relevant hazards. FDA’s data suggests that the information costs with respect to seafood quality control and food safety may be too great a burden for a substantial portion of seafood firms, such that self-regulation through HACCP may not be an effective regulatory model for these less sophisticated firms. Yet, some would argue that perhaps the most beneficial feature of HACCP is its mandate that food processors gain the sophistication needed to produce a safe food product, and that food processors, not

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<sup>167</sup> 60 Fed. Reg. at 65106.

<sup>168</sup> 60 Fed. Reg. at 65106-07.

<sup>169</sup> Food and Drug Administration, *FDA’s Evaluation of the Seafood HACCP Program for Fiscal Years 2002/2003*. Online at <http://www.cfsan.fda.gov/~comm/seaeval3.html>.

government, bear the responsibility for ensuring food safety.

Although HACCP purports to shift the regulatory burden to industry, substantial levels of industry non-compliance effectively shifts part of that burden back to FDA. After all, if significant numbers of seafood processors fail to meet federal safety standards, the Agency must increase, or at least adapt, its oversight and enforcement procedures in order to ensure a safe food supply. The implementation of HACCP itself also resulted in increased burdens on FDA. In the long term, HACCP was expected to reduce federal regulatory costs; but in the short term, FDA had to radically shift its regulatory approach, issue regulations and guidance, and retrain its inspection and enforcement personnel. Substantial deficiencies in the Agency's actions could jeopardize the gains to be realized through HACCP. Indeed, in a January 2001 report, the Government Accounting Office (GAO) reviewed FDA's implementation of HACCP, addressing numerous issues that undermine the system's effectiveness.<sup>170</sup> The report, provocatively entitled "Federal Oversight of Seafood Does Not Sufficiently Protect Consumers," suggests that FDA itself was ill-equipped to handle the administrative and regulatory burdens necessary for effective implementation of the seafood HACCP regulations.

One of the major problems identified by GAO was FDA's inability to adequately monitor the safety of imported seafood products which, in 1999, totaled an estimated 3.9 billion pounds of food.<sup>171</sup> Pursuant to the HACCP regulations, importers have the burden of ensuring that the seafood they import is safe and processed in compliance with a suitable HACCP plan.<sup>172</sup> Yet, the easiest way for an importer to meet that burden—obtaining the seafood from a country certified by FDA as having a compliance system equivalent to the U.S. system—had been foreclosed by FDA's inability to enter into an agreement or memorandum of understanding (MOU) with other countries certifying their compliance systems.<sup>173</sup> Consequently, importers were left with the task of acquiring documentation of affirmative steps taken by foreign seafood processors to ensure the safety of their seafood, a task at which most importers did not or could not succeed.<sup>174</sup> GAO found FDA's inspections at foreign plants and ports of entry, as well as FDA's enforcement actions against noncompliant firms, to be wholly inadequate to compensate for importers' failure to verify the safety of their imports.<sup>175</sup>

GAO found that another feature of the HACCP regulations prohibited FDA from effectively monitoring seafood processors' compliance. Unlike the low-acid canned food regulations, the HACCP regulations contain no requirement that seafood processors register with FDA. Without such a provision, the Agency resorted to identifying firms through such costly methods as the yellow pages, the trade press, and consumer complaints.<sup>176</sup> Consequently, FDA had no accurate record of the number of firms subject to the HACCP rule, nor did it have any cost-effective method of obtaining such records. Any number of firms simply escaped from federal oversight of their seafood operations.

Another major problem identified by GAO was the presence of certain gaps in the HACCP regulations, deliberately introduced by FDA in order to decrease its regulatory burden. For instance, FDA exempted

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<sup>170</sup> Government Accounting Office, *Federal Oversight of Seafood Does Not Sufficiently Protect Consumers* (January 2001). Online at <http://www.gao.gov/new.items/d01204.pdf>.

<sup>171</sup> *Id.* at 8.

<sup>172</sup> 21 C.F.R. § 123.3(g).

<sup>173</sup> See 21 C.F.R. § 123.12(a)(1); Government Accounting Office, *supra* note 170, at 24.

<sup>174</sup> See 21 C.F.R. § 123.12(a)(2); Government Accounting Office, *supra* note 170, at 26-29.

<sup>175</sup> Government Accounting Office, *supra* note 170, at 30-31.

<sup>176</sup> *Id.* at 14.

fishing vessels, carriers and retailers from the HACCP regulations by excluding them from the definition of “processor.”<sup>177</sup> FDA noted that the activities of these firms properly could be characterized as “processing”, but that the relatively low risk of hazards inherent in their activities did not warrant the enormous regulatory costs of ensuring their compliance with the HACCP rule. Specifically, the Agency reasoned that “the large size of the U.S. fishing fleet and the large numbers of carriers and retailers would overwhelm any rational Federal inspection system.”<sup>178</sup> GAO disagreed with FDA’s conclusions, warning that hazards could arise through the improper harvesting, transporting, “heading”, gutting, and freezing of fish aboard fishing vessels, as well as through improper temperature control at warehouses and storage facilities; the potential public health consequences warranted, in GAO’s opinion, that the currently exempt firms be required to adopt HACCP plans.<sup>179</sup>

Thus, the transition to HACCP left both the regulator and the regulated entity with burdens that each was unable to fully meet. Yet, despite these setbacks, the federal government remained steadfast in its devotion to HACCP as a regulatory tool. GAO did not call for a retreat from HACCP, but rather for “stronger implementation” of the system.<sup>180</sup> FDA responded by issuing a “mid-course correction” in order to address some of the weaknesses pointed out in the GAO report.<sup>181</sup> Any short-term failures would not be appropriated by the Agency to derail the perceived long-term benefits of HACCP.

## Part IX

Despite the difficulties in transitioning over to a HACCP system of regulation, the Agency continued to view HACCP with favor compared to alternative regulatory options. FDA proposed HACCP regulations for juice in 1998. The proposal was prompted, in part, by a series of high-profile cases of microbial contamination—in particular, a 1996 outbreak of *E. coli* in unpasteurized apple juice that resulted in the death of a child.<sup>182</sup> The proposed regulations revealed other potential hazards that were concerning the Agency, including the presence of pesticides and contaminants from soil, cans, and the manufacturing process in juice products.<sup>183</sup>

Over protests from industry, FDA adopted the juice HACCP regulations in 2001, declining to adopt more limited regulatory options such as increased inspections, new GMP regulations, mandatory pasteurization, better labeling, or increased industry education.<sup>184</sup> With juice, the Agency did not face the variety and complexity encountered with seafood production. FDA could have addressed the problem of microbial contamination by mandating heat treatment or pasteurization of juice products. Likewise, FDA could

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<sup>177</sup> 60 Fed. Reg. at 65112.

<sup>178</sup> *Id.*

<sup>179</sup> Government Accounting Office, *supra* note 170, at 14-16.

<sup>180</sup> *Id.* at 7.

<sup>181</sup> Food and Drug Administration, *FDA’s Seafood HACCP Program: Mid-Course Correction* (Feb. 13, 2001). Online at <http://www.cfsan.fda.gov/~comm/shaccp1.html>. FDA’s plan called for improvements in inspection, enforcement and guidance to industry; but the Agency did not amend its regulations to include within their scope fishing vessels, carriers and retailers, nor has it amended the regulations to address any of GAO’s other concerns.

<sup>182</sup> Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice; Food Labeling: Warning Notice Statements; Labeling of Juice Products; Proposed Rules, 63 Fed. Reg. 20449, 20450, 20452 (April 24, 1998).

<sup>183</sup> *Id.* at 20451-52.

<sup>184</sup> Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice; Final Rule, 66 Fed. Reg. 6137, 6140 (January 19, 2001).



have collaborated with the Environmental Protection Agency to address concerns about environmental contaminants and pesticides. So why did FDA choose HACCP?

The answer lies in HACCP's flexibility. HACCP allows food processors and regulators to target their limited resources towards those concerns or critical control points most likely to affect the safety and quality of the finished juice product. The juice HACCP final rule elaborates on these benefits:

"Flexibility in how to address identified hazards is inherent in HACCP systems. Even when producing comparable products, no two processors use the same source of incoming materials or the same processing technique, or manufacture in identical facilities. Each of these factors (and their many combinations) presents potential opportunities for contamination of the food. HACCP focuses the processor on understanding his own process and the hazards that may be introduced during that process, and identifying specific controls to prevent, reduce, or eliminate the identified hazards.

"The flexibility of the HACCP approach is a critically important attribute. This flexibility allows manufacturers to adjust CCP's, adjust techniques used to address CCP's when changes occur in the system (e.g., use of new ingredients), and readily incorporate new scientific developments (e.g., use of new control techniques, new preventive technologies, identification of new hazards). Another important strength of HACCP is the development of a plan written by the processor detailing the control measures to be used at CCP's. By developing a written plan, juice processors gain a working knowledge of their processing system, its effect on the food, and where in the system potential contamination may occur. Both the processor and the agency are able to derive the full benefits of a HACCP system. The hazard analysis and HACCP plan allow both the processor and the agency to verify and validate the operation of the system. HACCP's flexibility also permits processors to select the appropriate control measures in the context of how the whole system functions, allowing processors to use the most appropriate and economical methods to control food hazards that are reasonably likely to occur in their operation. The ability to choose among various control methods encourages research on and development of new and innovative technologies to better address individual situations."<sup>185</sup>

The flexibility of HACCP individualizes the approach manufacturers take towards ensuring food safety and quality, as well as the approach FDA takes towards each manufacturer's HACCP plan. The freedom inherent in this system allows manufacturers to experiment with new quality control methods, rather than simply adjusting their methods to comply with those specified by detailed regulations.<sup>186</sup> Experimentation is further encouraged through HACCP's verification requirement. Because food processors' HACCP plans must periodically be re-evaluated and verified, HACCP forces food processors and regulators to continuously inform themselves regarding the latest advances in the fields of food science and technology.<sup>187</sup> With current scientific and technical information at their fingertips, food processors are better able to create safer and more efficient quality control systems through experimentation.

Therefore, to paraphrase Justice Brandeis, HACCP allows the single courageous manufacturer to serve as a laboratory and try novel experiments.<sup>188</sup> At worst, the experimentation may only harm the manufacturer

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<sup>186</sup> The low-acid canned foods regulations with their detailed descriptions of proper retort equipment serve as an example of an inflexible regulatory scheme.

<sup>187</sup> 66 Fed. Reg. at 6141.

<sup>188</sup> See *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy

who invested time and money into a failed experiment; but at best, the single manufacturer may produce an innovation that may ultimately spread through the industry and benefit all manufacturers. By focusing manufacturers' attention on the production process rather than on the end product, and by requiring manufacturers to verse themselves in the latest scientific knowledge, HACCP provides the groundwork from which manufacturers can then build upon to improve their quality control systems. Thus, in a regulated industry, HACCP serves as an engine driving innovation.

FDA believed that this engine would drive innovation even among small businesses, which often bear the greatest burden in transitioning over to HACCP. FDA acknowledged that small businesses' "complete understanding of what constitutes full implementation of a HACCP system [may not be] immediate," but nevertheless believed that small processors could and should be able to master the HACCP concept.<sup>189</sup> Through HACCP, small business would benefit from the forced self-education on science-based analysis and control of juice hazards, allowing them to improve the quality and safety of their products.

## Part X

Despite FDA's enthusiasm for the dynamic and flexible HACCP system, industry has not always been so receptive to the idea. A recent example involves current good manufacturing practices (CGMPs) for dietary supplements. FDA suggested that HACCP might be an appropriate regulatory approach to dietary supplement CGMPs; the Agency noted, "[B]ecause of the wide variety of dietary ingredients and dietary supplements and because of the heterogeneous composition of the dietary supplement industry, CGMPs based on HACCP principles may provide a more flexible and less burdensome regulatory framework for manufacturers and distributors than the approach set out in the industry submission."<sup>190</sup> Yet, comments from industry revealed widespread opposition to HACCP, prompting FDA to abandon any plans to institute a formal HACCP requirement for dietary supplement manufacturing.<sup>191</sup>

At face value, FDA's decision to propose traditional CGMP requirements for dietary supplement suggests a defeat for the HACCP concept; it also suggests that future application of HACCP may be restricted only to certain categories of high-risk foods such as seafood and juice. However, FDA's decision to forego a *formal* HACCP requirement does not preclude the possibility of HACCP concepts comprising a substantial portion of the proposed CGMP regulations. Indeed, a closer look at the proposed dietary supplement CGMP regulations indicates that FDA has not retracted its support for HACCP. Take, for example, proposed regulation 111.45:<sup>192</sup>

Sec. 111.45 What requirements apply to establishing a master manufacturing record?

(a) You must prepare and follow a written master manufacturing record for each type of dietary ingredient or dietary supplement that you manufacture and for each batch size to ensure uniformity from batch to batch. The master manufacturing record must:

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incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory, and try novel social and economic experiments without risk to the rest of the country.")

<sup>189</sup> 66 Fed. Reg. at 6145.

<sup>190</sup> Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements; Proposed Rule, 68 Fed. Reg. 12157, 12173-74 (March 13, 2003).

<sup>191</sup> *Id.* at 12174.

<sup>192</sup> *Id.* at 12259.

- (1) Identify specifications for the points, steps, or stages in the manufacturing process where control is necessary to prevent adulteration; and
- (2) Establish controls and procedures to ensure that each batch of dietary ingredient or dietary supplement manufactured meets those specifications.

(b) The master manufacturing record must include the following information:

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(8) Written instructions including, but not limited to, the following:

- (i) Specifications for each point, step, or stage in manufacturing the dietary ingredient or dietary supplement necessary to prevent adulteration;
- (ii) Sampling and testing procedures;
- (iii) Specific actions necessary to perform and verify points, steps, or stages, necessary to meet specifications and otherwise prevent adulteration, including, but not limited to, one person weighing or measuring a component and another person verifying the weight or measure and one person adding the component and another person verifying the addition;
- (iv) Special notations and precautions to be followed; and
- (v) Corrective action plans for use when a specification is not met.

(c) You must have the quality control unit review and approve each master manufacturing record and any modifications to a master manufacturing record.

(d) You must keep master manufacturing records in accordance with Sec. 111.125 [which requires firms to keep records for 3 years, and make them available to FDA for inspection and copying upon request].

As demonstrated by this proposed regulation, the HACCP principles are surreptitiously embedded within the proposed CGMP regulations. Under proposed section 111.45, the “master manufacturing record” constitutes a crude HACCP plan. In this crude plan, the manufacturer must identify and establish controls for steps in the manufacturing process “where control is necessary to prevent adulteration”—i.e., critical limits and critical control points (§111.45(a)). The manufacturer also must institute appropriate monitoring of the control points, as well as corrective action plans when control is not maintained (§111.45(b)(8)). FDA embodied the verification requirement within proposed section 111.45(c), as indicated by the Agency’s comments to the proposed rule.<sup>193</sup> FDA placed the documentation requirement in proposed section 111.125 (referenced in § 111.45(d)).

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<sup>193</sup> *Id.* at 12204 (“The quality control unit review will ensure that necessary inprocess [sic] verifications and testing instructions are included in the master manufacturing record”); FDA also asked for comments as to whether it should require verification procedures for computerized equipment. *Id.* at 12194.

Proposed 111.45 does not require a hazard analysis. However, the entire body of proposed CGMP regulations themselves constitute a crude analysis of the various hazards potentially affecting the typical dietary supplement manufacturing process—e.g., microbes and poor hygiene (proposed § 111.10), poor sanitation (proposed § 111.15), poor plant design and construction (proposed § 111.20), faulty or improper equipment or utensils (proposed § 111.25), and faulty or improper automatic, mechanical or electronic equipment (proposed § 111.30).<sup>194</sup> Thus, the major HACCP concepts are all present.

The proposed dietary supplement CGMP regulations may lack the purity and bite of HACCP regulations; furthermore, the covert application of HACCP principles may not sufficiently focus manufacturers' attention on their individual manufacturing processes, and may not provide the desired incentive for industry self-education and innovation. Yet, given the political context in which FDA operates, the proposed regulations perhaps represent the most effective manner of introducing the HACCP regulatory strategy to an industry opposed to radical change.

In conclusion, the future of HACCP looks bright, especially given the potential finalization of the dietary supplement CGMP regulations. Additionally, FDA has stated its intention to revisit its food CGMP regulations, opening up new possibilities for the expansion of HACCP.<sup>195</sup> With respect to the food CGMP regulations, the Agency asked, "What concepts or underlying principles should guide FDA's adoption of new preventive controls [for food manufacturing]?"<sup>196</sup> Certainly, the concepts of statistical quality control and HACCP should play the major roles in guiding FDA's choice of regulatory scheme.

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<sup>194</sup> *Id.* at 12253-56.

<sup>195</sup> Food; Current Good Manufacturing Practice Regulations; Public Meetings, 69 Fed. Reg. 29220 (May 21, 2004).

<sup>196</sup> *Id.* at 29221.